

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO.
2:12-MD-02327

THIS DOCUMENT RELATES TO:

CAROLYN LEWIS

CIVIL ACTION NO.
2:12-cv-04301

February 13, 2014
Charleston, WV

TRANSCRIPT OF TRIAL - DAY 4
BEFORE THE HONORABLE **JOSEPH R. GOODWIN**,
UNITED STATES DISTRICT JUDGE, AND A JURY

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1	I N D E X	
2		<u>Page</u>
3	<u>Plaintiff's Witnesses</u>	
4	JAMES HART (by video)	17
5	MENG CHEN (by video)	26
6	GENE KAMMERER (by video)	28
7	JOERG HOLSTE (by video)	42
8	UWE KLINGE	
9	Direct Examination	43
10	Cross Examination	92
11	Redirect Examination	109
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

MORNING SESSION

(Out of the presence and hearing of the jury:)

3 THE COURT: Okay. Let me first put on the record
4 rulings on the spoliation issues. In her February 4, 2014
5 order, Judge Eifert thoroughly examined the evidence of
6 spoliation in this multi-district litigation bellwether -- in
7 this multi-district litigation. She determined that the
8 evidence did not warrant default judgment or adverse
9 inferences in all cases. However, she recommended that I
10 allow the plaintiff the opportunity to introduce evidence
11 regarding Ethicon's loss of relevant documents on a
12 case-by-case basis and, when appropriate, to tender an adverse
13 inference instruction.

14 I have considered the parties' written and oral
15 arguments. The fact is that Ethicon's duty to preserve
16 documents was not, and I find it was not, triggered until
17 April 30, 2007. The plaintiff's evidence pre-dates this
18 duty. Judge Eifert specifically found that, quote, The
19 MedScand materials were lost or discarded in 2006 before
20 Ethicon had a duty to preserve evidence relevant to this MDL.
21 Accordingly, the missing MedScand documents do not support a
22 finding of spoliation. Unquote.

23 In any event, I have already allowed the plaintiffs to
24 introduce evidence that Miss Angelini's documents were lost or
25 destroyed, but beyond that, I will not permit the plaintiff to

1 introduce any further evidence on the issue of spoliation,
2 including the playing of Mr. Mittenthal's deposition which
3 raised no new issues beyond an attempt by -- an apparent
4 attempt by plaintiffs to plow old ground.

5 Show the plaintiff's objection.

6 Did you have something that you wanted to put on the
7 record?

8 MS. JONES: Yes, Your Honor. If I --

9 THE COURT: We may have a long day to put stuff on
10 the record. I don't know.

11 MS. JONES: Well, I'm going to do this really
12 quickly because we have agreed. The plaintiffs know we have
13 some objections to the depositions that we worked diligently
14 with on, Your Honor, and with a smile, and we have -- we need
15 to make these objections to preserve the record. Your Honor
16 rules, we've got one cut that puts the stuff in and one cut
17 that takes it out.

18 THE COURT: All right.

19 MS. JONES: The first is --

20 THE COURT: Do I need a transcript?

21 MS. JONES: I don't think so, Your Honor. If you
22 do, we have them. The first is that we object to the
23 introduction of medical device reports and reports of patients
24 that have come in, other than Mrs. Lewis in this case, on the
25 grounds that those medical device reports are hearsay,

1 unreliable, and not substantially similar to Mrs. Lewis's
2 complaints.

3 And the testimony that relates to this is in the
4 testimony of Ms. Chen, and specifically it is that testimony
5 related to Plaintiff's Exhibit 700, the testimony of
6 Mr. Kammerer, and it's the testimony that relates to
7 Plaintiff's Exhibits 536 and 545, which are, in fact, the
8 issue reports that are the subject of the testimony.

9 So that's the first objection with respect --

10 THE COURT: Can I see it?

11 MS. JONES: Yes, Your Honor.

12 THE COURT: May I? I think I can.

13 MS. JONES: This is the -- that's the one with
14 respect to Miss Chen.

15 THE COURT: Mr. Cartmell, do you want to address
16 that?

17 MR. CARTMELL: Yes. With respect to the Chen --

18 (Remarks off the record)

19 MR. CARTMELL: We think, Your Honor, you just looked
20 at the issue report from Dr. Kammerer's deposition, and that
21 is, what happens is there are calls from physicians and
22 patients outside the company. They go into a database called
23 Remetrex. They're tracked within the company. And Kammerer
24 is an engineer. He testified that the frayed edges of the
25 mesh are not a problem. He doesn't believe they can cause any

1 clinical issues with women.

2 Those documents are related to the frayed edges and the
3 fact that they can cause clinical issues in women, pain and
4 other issues. Part of our case is that the frayed edges and
5 the particle loss and the roping and curling and all that
6 stuff do in fact cause harm to women, their -- there is
7 clinical benefit, the defense is, that there is not. And so
8 those are relevant to our case related to notice for the
9 company, related to the negligence case that the company had
10 knowledge related to the defect with the mechanically cut mesh
11 and did not do anything to change or alter the mesh or do a
12 study, which he will testify to, Mr. Kammerer will testify to,
13 related to that.

14 So we think it's highly probative that they did that,
15 especially given that their defense is that none of this does
16 anything; it's just cosmetic.

17 MS. JONES: And, Your Honor, with all due respect to
18 what Mr. Cartmell says, it doesn't overcome the hearsay and
19 unreliability issues with respect to the report. If it is to
20 be offered for the issue of notice only, we would ask for an
21 instruction to that effect.

22 THE COURT: Is this -- I don't quite understand how
23 this is presented to the witness and how it is in the, I
24 guess, the videotape deposition.

25 MR. CARTMELL: Okay.

1 THE COURT: Could you explain that for me?

2 MR. CARTMELL: Yes. There is a -- I'm trying to
3 remember the order, but I think it's, "Have you ever heard
4 that the frayed edges can cause pain or tissue problems or
5 damage or clinical issues in women?" And I think he says,
6 "Yes." I will check that to make sure, but then there is a
7 production of the issue report and then there is,
8 "Mr. Kammerer, had you ever heard that the frayed edges of the
9 mesh while you were the lead engineer, technical engineer
10 could perforate a woman's vagina as is stated in the issue
11 report?"

12 THE COURT: And he says what?

13 MR. CARTMELL: I think he says, "That's impossible."

14 THE COURT: He says what?

15 MR. CARTMELL: He says, "That's impossible. It
16 doesn't happen."

17 THE COURT: Okay. And then is he confronted with
18 this at that point?

19 MR. CARTMELL: He's confronted with it before, and
20 then I said, "Were you ever told," and he says -- he says, "I
21 don't" -- I think he says, "I wasn't, but it's impossible that
22 that was the frayed edges."

23 MS. JONES: I can hand you, Your Honor, the
24 testimony if it would help. It's at pages 167 through 1 --
25 actually, it goes through the two issue reports, 167 through

1 roughly 177 of his testimony, if you'd like to just see that.

2 THE COURT: These are business records of Ethicon,
3 is that correct --

4 MS. JONES: Yes, Your Honor.

5 THE COURT: -- that were furnished, and they're used
6 to confront an Ethicon employee?

7 MR. CARTMELL: Yes, Your Honor.

8 THE COURT: And I will allow it and overrule the
9 objection. I will give a limiting instruction that these
10 documents are only -- well, I don't see that the documents
11 come in, but the questions and answer related to the documents
12 may come in, and I will tell the jury that Exhibit Number 536
13 and 545 were offered for the purpose of showing notice. Of
14 course, if you want to re-word it, I'll consider some other
15 wording.

16 MR. CARTMELL: I'm fine with that, Your Honor.

17 THE COURT: Okay. Anything else?

18 MS. JONES: Well, those documents specifically
19 related to Mr. Kammerer -- excuse me -- to Mr. Kammerer,
20 Judge. You also have another exhibit that was -- I think
21 Robin handed you another exhibit. It's the same issue. It's
22 with respect to Miss Chen. And I apologize, Your Honor.
23 You've got the exhibit, so I can't see what the exhibit number
24 is, but it's an issue report and an analysis of a report by
25 the plaintiff.

1 THE COURT: Number 700; is that right?

2 MS. JONES: Yes.

3 THE COURT: I haven't read the testimony, but is it
4 used in a similar fashion?

5 MR. CARTMELL: Yeah, this is a little different,
6 Your Honor, but this was Dr. Chen's, who was in charge of
7 monitoring the adverse events, and she went and did a review
8 of all the adverse events for her superiors. One thing she
9 looked at is the long-term complications. Am I on the wrong
10 one?

11 MS. JONES: It's just this one over here.

12 MR. CARTMELL: I apologize.

13 MS. JONES: It's just the -- we have worked the
14 other part out that Mr. Cartmell was talking about. We
15 redacted it. This is only on the issue of the adverse event
16 report, and this is the one where the plaintiff underwent a
17 pelvic floor repair procedure nearly four years ago to treat a
18 cystocele of the bladder, and this is the analysis that Dr.
19 Chen performs with respect to that adverse event that's
20 reported to the company.

21 MR. CARTMELL: That's right. Sorry. That is a
22 different, different adverse event report. It is a single --
23 same argument, Your Honor, just a different document.

24 THE COURT: In this event, it is an analysis of a
25 report of an adverse event by an employee at Ethicon reacting

1 to that adverse report; is that right?

2 MS. JONES: Essentially, Your Honor, yes.

3 THE COURT: This talks about mesh of unknown origin.

4 What does that mean?

5 MR. CARTMELL: Well, I don't know what that means,
6 but it is actually the Prolene mesh in the TVT that is an
7 adverse event is my understanding from that.

8 THE COURT: I don't see that.

9 MR. CARTMELL: A Gynecare TVT abdominal sling was
10 placed during the procedure. That's the actual sling that was
11 used and caused the adverse event. I do see where you are
12 saying a device of unknown origin, but I don't think it's
13 disputed that it was the TVT mesh.

14 MS. JONES: Well, I think that goes, frankly, to the
15 unreliability of the report and the hearsay objection that
16 we've made.

17 THE COURT: Is this lady here? Is she testifying?

18 MR. CARTMELL: This is her. This is Dr. Chen.

19 MS. JONES: This is Dr. Chen.

20 THE COURT: And she is testifying --

21 MR. CARTMELL: About this.

22 THE COURT: -- about this is in a videotaped
23 deposition.

24 MR. CARTMELL: Yes, Your Honor.

25 THE COURT: And this is a document -- forgive my

1 ignorance. Is this part of her testimony or is this a record
2 that she made in reaction to an adverse event about which she
3 is asked to testify?

4 MR. CARTMELL: The latter, what you just said.

5 THE COURT: It seems to me that the entirety of this
6 delves into areas that are not relevant, but I don't know how
7 it's being used, so I guess I'm going to have to look at the
8 transcript.

9 MR. CARTMELL: Look at the transcript? I think we
10 can --

11 MS. JONES: I have the transcript right here. I'm
12 trying to find exactly where that -- do you have a page on
13 this?

14 THE COURT: In the very conclusion, she says she
15 can't confirm the origin of the mesh which extruded into the
16 bladder, and previously she says, "Our mesh can't do that
17 unless the bladder has been injured" or something like that.
18 I just need to see the testimony.

19 MS. JONES: I'm trying to find if we have a --

20 THE COURT: All of the jurors are here.

21 THE CLERK: Yes.

22 MS. JONES: I think it starts where it says Exhibit
23 3324. It's back toward the back.

24 THE COURT: This is talking about two pictures and
25 not about this exhibit.

1 MS. JONES: I may have given you the wrong exhibit
2 number.

3 THE COURT: The exhibit number I have is 700 on this
4 page. Let me give you both documents back.

5 MR. CARTMELL: Your Honor, it starts at page 310,
6 line 10.

7 THE COURT: Does it relate to Exhibit 700?

8 MR. CARTMELL: Yeah. That was a trial exhibit and
9 we were telling you the deposition exhibit. Sorry about that.

10 THE COURT: All right. Starts at page what?

11 MS. JONES: 310.

12 THE COURT: All right.

13 MS. JONES: It's about three-fourths of the way
14 down.

15 THE COURT: Just so I'm not overruling on the wrong
16 thing, the exhibit which is marked 700 that you showed me is
17 Exhibit 3333?

18 MR. CARTMELL: Yes, Your Honor.

19 THE COURT: The -- it seems to me that I will admit
20 the examination. The exhibit appears to say things
21 completely -- that contradict the characterization of the
22 exhibit and examination, but that's appropriate for cross or
23 examination, but I will allow it.

24 MS. JONES: Your Honor, may I just quickly make two
25 other points? We have agreed with respect to the various

1 transcripts that are ready to go. A couple of things I want
2 to make clear for the record that we discussed with
3 plaintiff's counsel --

4 THE COURT: Yes.

5 MS. JONES: -- we have not insisted upon the
6 exclusion and redaction of every complication that the
7 plaintiff did not suffer from in this case with the
8 understanding that we will in fact ask Your Honor at an
9 appropriate point to instruct the jury that their verdict
10 should be premised upon the injuries that the plaintiff
11 actually had. And we just don't want to waive anything by
12 bringing it up.

13 THE COURT: Is that agreeable?

14 MR. CARTMELL: We understand that they're going to
15 make that request.

16 THE COURT: Right.

17 MR. CARTMELL: Our -- that's agreeable. Our -- for
18 the record, although our position is obviously we think all of
19 the risks need to be weighed against all of the benefits.

20 THE COURT: I understand. All right. That's very
21 good, and I really appreciate the obvious hard work that went
22 into this.

23 MS. JONES: I need 15 more seconds, Your Honor.

24 THE COURT: Sure.

25 MS. JONES: There are also cumulative designations

1 in here. We've advised counsel that we think that they're
2 cumulative. We've not insisted that they be taken out, but
3 they come out of their time. And if they choose to play the
4 cumulative stuff, it's at the peril that we will object in the
5 context of their live witnesses. That's one.

6 And, finally, Your Honor, and this has nothing to do with
7 the plaintiff's counsel. It does have to do with me. We have
8 made these agreements and stipulations with respect to both of
9 the exhibits and the deposition cuts with respect to this case
10 and this case alone.

11 THE COURT: Understood.

12 MS. JONES: I want it on the record that we are not
13 making these agreements or these cuts for the remainder of the
14 MDL or for any other state court litigation. This is very
15 specifically under the circumstances of this case.

16 THE COURT: I understand, and I certainly agree that
17 under the trial pressures and at the request of the Court, you
18 have made agreements which are for the purposes of this trial
19 only and do not bind either party to the agreements made in
20 future endeavors.

21 I will be proposing something along the lines of what I
22 suggested yesterday, and the parties may agree to a
23 modification, agree to some other procedure. I'm not trying
24 to rule with an iron hand. I just want to avoid the same
25 hassle that we had today -- or not today, this week.

1 MS. JONES: What I suggest, Your Honor, is that
2 Mr. Cartmell and I will be happy to sit down with you
3 informally and work something out.

4 THE COURT: That sounds good.

5 MS. JONES: I think we have both learned. We now
6 know what the problems have been, and neither one of us takes
7 responsibility for them, but we all understand that we all
8 bear a part of that. But I think we know of ways that this
9 can be remedied and we don't fool with it again.

10 THE COURT: All right. I'll look forward to that.

11 Let's bring the jury in.

12 MR. CARTMELL: Thank you.

13 MR. FREESE: Your Honor --

14 THE COURT: Yes, sir?

15 MR. FREESE: -- before we bring the jury in, Robin
16 just gave me the current exhibit list, and it doesn't appear
17 that we offered the Angelini exhibits at the deposition
18 yesterday. I was wondering if we could take care of that now
19 before we bring the jury in. I know Your Honor wants to keep
20 everything falling smoothly.

21 THE COURT: Yes, you may.

22 (Counsel conferred privately off the record)

23 THE COURT: I'm going to consider you do this at the
24 morning break. I've told the jury that I would be singing and
25 dancing at 9:00. Bring the jury in. It may have appeared to

1 you all -- and if it hasn't, please understand I hate
2 last-minute stuff.

3 (Jury In)

4 THE COURT: Good morning, ladies and gentlemen, to
5 this lovely sunny morning in Charleston, West Virginia.
6 Please be seated. I realize it's ten after and you've missed
7 my singing and dancing.

8 We are ready to proceed, and I think things will go very
9 smoothly today.

10 Mr. Cartmell, do you want to call your next witness?

11 MR. CARTMELL: Yes, Your Honor. Dr. James Hart,
12 chief medical officer at Ethicon.

13 THE COURT: All right.

14 MS. JONES: Your Honor, we've exchanged -- we just
15 found that there was a mistake in -- this has been uploaded
16 and added. We're trying to -- we are remedying that. We're
17 going to go ahead and play it, but it's something the
18 plaintiff's counsel may stop it. It's just a technological
19 mistake.

20 THE COURT: If you need to stop it to fix something,
21 go ahead and do that.

22 MR. FREESE: Thank you, Your Honor.

23 (The video of James Hart was played.)

24 MS. JONES: I'm sorry, Your Honor. We've got a
25 glitch here. We've got something that was not part of this, I

1 think.

2 MR. FREESE: I was asking that he --

3 THE COURT: I'm sorry. I can't hear you.

4 MR. FREESE: I was merely asking that he expand the
5 document so we can see.

6 THE COURT: Well, work out whatever the problem is
7 before you show anything else.

8 (Counsel conferred privately off the record)

9 (The video of James Hart was resumed)

10 MR. FREESE: Your Honor, we can end our examination
11 here and go to 810 and play the examination by the defendant.

12 THE COURT: Is that correct?

13 MS. JONES: I'm sorry?

14 THE COURT: Take it down.

15 (Counsel conferred privately off the record)

16 MR. FREESE: Thank you, Your Honor.

17 MS. JONES: We just need the cuts. He's the lead
18 part of his thing. We just need to start on the direct
19 examination.

20 THE COURT: All right. Ladies and gentlemen, back
21 to basics. When we have a live witness, the plaintiff, having
22 the burden of proof, puts on the witness, asks some questions,
23 stops, defendants cross-examine. Then plaintiffs can come
24 back and redirect in any areas that were contained in the
25 cross-examination. Where we are with this witness is they've

1 decided that this is -- the plaintiffs have decided this is
2 the end of his direct examination. Now the defendants will
3 move into playing the part which is the cross-examination of
4 this witness.

5 It's a little more confusing than that, but because the
6 parties -- but there you go.

7 MS. JONES: Technologically we're ready to go, Your
8 Honor.

9 THE COURT: All right. Go ahead.

10 (The video of James Hart was resumed.)

11 MR. CARTMELL: I'm in agreement the objections will
12 be taken out on both sides.

13 THE COURT: I've noticed that since you all started
14 playing videotapes. They should have all been taken out.

15 MS. JONES: Should have been, and we apologize, Your
16 Honor.

17 THE COURT: Well, it's happened in the ones they
18 did, too, so I'm not pointing fingers at anybody. Do your
19 best. Let's go.

20 (The video of James Hart was resumed.)

21 MR. COMBS: That concludes the examination.

22 MR. CARTMELL: That's the end of the videotape, Your
23 Honor.

24 THE COURT: All right. Instead of getting into the
25 next videotape, let's take our morning break a little early.

1 We'll take 15 minutes.

2 During your break, enjoy a doughnut. You need it for
3 warmth. Don't discuss the case among yourselves, permit
4 anyone to discuss it with you or in your presence. Don't use
5 any social media or electronic means to communicate with
6 anyone in any form about anything in this case.

7 Court will be in recess for 15 minutes.

8 (Recess)

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1 (In open Court following the recess. The jury is
2 not present.)

3 THE COURT: I understand we have a matter to
4 take up?

5 MR. CARTMELL: And, Judge, if you wouldn't mind
6 if we could do it at sidebar, that would be best.

7 THE COURT: Sure.

8 SIDEBAR CONFERENCE:

9 THE COURT: All right.

10 MR. CARTMELL: Your Honor, if you didn't -- you
11 probably did notice in that video there was Dr. Hart's
12 background with the company three separate times, and our
13 video designations would have been one quick cut off that
14 for a matter of a minute or two.

18 MR. CARTMELL: I just wanted to make a record.
19 That was my impression, that that time -- these things are
20 being inserted, we feel, to make us look bad. The jury is
21 hearing the man being introduced the same way three
22 different times. Our understanding is that your ruling is
23 that this can be contextual and they can add that into the
24 depositions. I believe that it is not.

25 THE COURT: I didn't rule on that at all. I

1 never did rule on that. I didn't rule on anything in this
2 deposition.

3 MR. CARTMELL: Well, I guess I understand that.
4 My understanding has been that the rulings from you all
5 along have been, I guess, that they're going to be able to
6 play their portions of the depositions, and that's the way
7 we've been operating, as we've been meeting and conferring
8 together. So we are letting them get back into things
9 that we would not -- it's duplicative.

10 I know you cannot stand duplicative testimony. I
11 just wanted to make sure that that is in the record.

12 THE COURT: Mr. Freese asked the same question
13 eight times, eight separate times, the same question.
14 That wasn't objected to. I didn't rule on it.

15 I did notice that we went over some of the same
16 positions that the medical director had three times.

17 I'm not excited about any of that. I don't like it.
18 But whoever played it, it's going to be their time.

19 MR. CARTMELL: Okay. Could we get
20 clarification, then, for future videos, potentially?

21 THE COURT: Uh-huh.

22 MR. CARTMELL: That if they add in duplicative
23 stuff, we'll get a chance to visit --

24 THE COURT: Whenever they play their section of
25 the video, that will take up their time. Whenever you

1 play your section, that's your time.

2 MR. CARTMELL: And if they add in, like, their
3 multiple minutes of their testimony on our side when we're
4 asking questions, can we get relief and that can be
5 charged to them?

6 THE COURT: You mean when they're cross-
7 examining the witness?

8 MR. CARTMELL: When we are cross-examining the
9 witness like that, and my question would have been, with
10 Dr. Hart, tell us your history with the company, and it
11 would have been one time. But then, when they add in
12 another time and a third time, can they be credited with
13 that, or can they not do that? Can we get a ruling from
14 the Court that if it's duplicative, that that cannot come
15 into the video?

16 THE COURT: I didn't notice it -- I did not see
17 anything in this video that was of sufficient length to
18 warrant a redo or a ruling on it. If, in the future, you
19 have a problem with that, and you can't resolve it before
20 you get here, then let's get out the transcript and go by
21 the transcript.

22 MR. CARTMELL: Okay.

23 THE COURT: And I have never said that I
24 wouldn't rule on it. I am not a video editor, and I'm not
25 going to stop and edit videos. But I certainly will take

1 the transcript, let you put a reader on the stand, I will
2 hear objections to the extent they're made.

3 Now, if it was taken for the purpose of trial, the
4 objection should have been made at the time it was done.

5 MR. CARTMELL: Right.

6 THE COURT: I don't understand this. I've
7 never experienced this with experienced counsel. I'm
8 surprised. Every minute of yesterday was a full day and
9 somebody's credited with it. Today's a full day and
10 somebody's going to be credited with it. In the end of
11 nine days, the case is going to be over. Spend it however
12 you like.

13 I'm not happy with you, but we'll do the best we
14 can.

15 (Court conferring with Law Clerk off the record.)

16 To the extent that the defendants have designated
17 parts of your examination, if that's what you're saying --

18 MR. CARTMELL: That is. I didn't make it
19 clear, I guess. It's our questioning.

20 THE COURT: Then that goes against their time.
21 If they designated it, it's theirs. Okay?

22 MR. CARTMELL: That's what I was asking.

23 MR. COMBS: We have been operating under that
24 assumption the entire time.

25 THE COURT: Okay. Well, inform the highly

1 qualified time-keepers that that's the deal, and my -- I
2 will go up and finish another couple sips of coffee and I
3 will be a lot nicer the next time you talk to me.

4 MR. CARTMELL: Thank you, Judge.

5 END OF SIDEBAR CONFERENCE.

6 MR. COMBS: Maybe just before the you bring the
7 jury in --

8 THE COURT: Sure.

9 MR. COMBS: -- we could just spend a second on
10 the record about the exhibits.

11 THE COURT: Sure. Go ahead.

12 MR. COMBS: The next witness that's going to be
13 played by video, it's my understanding, is Dr. Chen. Last
14 night we did meet and confer regarding the exhibits that
15 were going to be used in Dr. Chen's deposition. The
16 parties have agreed to a redact.

17 On 690 the parties have agreed to a redact. On 686.
18 On Exhibit 176 there was no objection. The defendant's
19 obviously objected to 700, and the Court ruled that it was
20 admissible. So, I think that covers all the exhibits.

21 MR. CARTMELL: I agree.

22 THE COURT: All right. You may proceed.

23 It's time to bring the jury in.

24 (The jury entered.)

25 THE COURT: Thank you, ladies and gentlemen.

1 Please be seated.

2 Call your next witness, please.

3 MR. CARTMELL: Your Honor, plaintiff calls
4 Dr. Meng Chen, associate medical director at Ethicon.

5 (The videotaped deposition of Meng Chen was played.)

6 MR. CARTMELL: Your Honor, that's the end of
7 the plaintiff's presentation of Dr. Chen.

8 THE COURT: All right.

9 MR. COMBS: Judge, there's very brief
10 questioning that's being cued up now.

11 MS. JONES: Judge, there's a very brief
12 questioning on behalf of the defendant.

13 THE COURT: Okay.

14 (Videotaped deposition of Dr. Chen continues.)

15 MR. COMBS: Judge, that ends the questioning
16 from both parties regarding this witness.

17 THE COURT: That concludes this witness?

18 MR. CARTMELL: Yes, your Honor.

19 THE COURT: All right. Thank you, very much.

20 Call your next witness.

21 MR. CARTMELL: Dr. --excuse me, Gene Kammerer,
22 who is an engineer at Ethicon, by video.

23 THE COURT: All right.

24 MR. COMBS: Judge, could we just approach very
25 briefly?

1 THE COURT: Sure.

2 SIDEBAR CONFERENCE:

3 MR. CARTMELL: I may have misunderstood you
4 this morning, your Honor. Phil just came over and said
5 the issue reports that were argued this morning were out
6 as far as being able to be shown. I guess I had -- I had
7 thought that your ruling was that they could be shown, but
8 that you were going to give an instruction to the jury.

9 MR. COMBS: Judge --

10 THE COURT: My ruling was that you could ask
11 her about those documents --

12 MR. CARTMELL: Okay.

13 THE COURT: -- in testimony, and I would then
14 instruct the jury that they should consider these
15 documents for the purpose of notice to the company of such
16 an event.

17 MR. CARTMELL: Right.

18 THE COURT: Or words to that effect.

19 MR. CARTMELL: Okay.

20 THE COURT: But I don't know how it is on the
21 video, so --

22 MR. CARTMELL: They just show the highlighted
23 portions of what is being talked about up on the screen.
24 There's nothing but that.

25 THE COURT: I'm going to let you do it. Let's

1 go.

2 MR. CARTMELL: Thank you.

3 END OF SIDEBAR CONFERENCE.

4 (Video deposition of Gene Kammerer played.)

5 MR. CARTMELL: Your Honor, this is a good
6 breaking point if we want to have a lunch break.

7 THE COURT: All right, ladies and gentlemen,
8 before we take lunch, during an earlier part of this
9 witness' testimony he was shown a couple of issue reports
10 which he said he wasn't familiar with, but you may
11 consider those issue reports and the portions that were
12 pointed out to you as evidence that Ethicon had notice of
13 the substance contained in the reports. But you may not
14 consider them for any other purpose, that is, you may not
15 consider them to be evidence of the truth of the matters
16 reported.

17 Now, it's time for lunch, slip-sliding away across
18 the street. I asked the Clerk of Court about buying your
19 lunch, and apparently Uncle Sam is too tight to do that.
20 So, I'm going to -- it's ten after. We'll try to start at
21 1:15. If you can't comfortably get across and get back by
22 1:15, I'll understand, but we'll do our best.

23 Don't discuss the case among yourselves, permit
24 anyone to discussion with your or in your presence. Don't
25 read, watch, or listen to anything about it. Don't use

1 any electronic media of any kind.

2 I'll see you back here at 1:15.

3 Court stands in recess.

4 I want to ask you, and we can talk it over during
5 lunch -- looks like it's going to snow tomorrow, too, or
6 more. I can have somebody run and get your lunch
7 tomorrow, if you pay for it. So, talk among yourselves if
8 you want me to do that.

9 I'll see you back here at 1:15.

10 (Luncheon recess.)

11 (During the luncheon recess Mr. Faes for the
12 plaintiffs, Mr. Combs for the defendant, the Clerk and the
13 Court Reporter participated in the following bench
14 conference outside the presence of the Court and jury.)

15 MR. FAES: These are all from the Laura
16 Angelini deposition. The first exhibit is Plaintiffs'
17 1963, which is the March 5th, 1997 Medscand agreement.

18 MR. COMBS: No objection.

19 MR. FAES: The second exhibit is Plaintiffs'
20 1965, which is the asset purchase agreement dated November
21 15th, 1999.

22 MR. COMBS: No objection.

23 MR. FAES: The next exhibit is Plaintiffs'
24 1966, which is an exhibit titled Payments to Medscand.

25 MR. COMBS: No objection.

1 MR. FAES: Next exhibit is Plaintiffs' 1971,
2 titled Payments to Ulmsten as Consultant.

3 MR. COMBS: No objection.

4 MR. FAES: The next exhibit is Plaintiffs'
5 1970, which is a spreadsheet of payments to Prof. Nilsson.

6 MR. COMBS: No objection.

7 MR. FAES: The next exhibit is Plaintiffs'
8 1971, which is titled Payments to Ulmsten as Consultant.

9 THE CLERK: You've already got that.

10 MR. COMBS: We've already got that.

11 MR. FAES: The next exhibit is Plaintiffs' 858,
12 which is an email, Subject: ICS Submission.

13 MR. COMBS: No objection.

14 Plaintiff's Exhibit 1885 is a learned treatise that
15 was displayed on the video with the witness.

16 THE CLERK: I'll hold on to it and then give it
17 back.

18 MR. COMBS: Thank you.

19 MR. FAES: Did I give you 858?

20 THE CLERK: Yes, you did.

21 MR. FAES: The next exhibit is Plaintiffs' 93,
22 which is a July 30th, 1998, Summary of Key Points.

23 THE CLERK: That was 93, correct.

24 MR. COMBS: No objection.

25 MR. FAES: The next exhibit is Plaintiffs' 669,

1 which is titled The History of TVT.

2 MR. COMBS: No objection.

3 MR. FAES: And that's the end of the Laura
4 Angelini exhibits.

5 THE CLERK: Okay.

6 MR. FAES: Okay, the first one for James Hart
7 is Plaintiffs' 1256, which is the curriculum vitae of
8 James C. Hart.

9 MR. COMBS: No objection.

10 MR. FAES: Next exhibit is Plaintiffs' 1297,
11 which is the Johnson & Johnson credo.

12 MR. COMBS: No objection.

13 MR. FAES: The next exhibit is Plaintiffs' 759,
14 which is an email entitled IIS Policy.

15 MR. COMBS: No objection.

16 THE CLERK: Thank you.

17 MR. FAES: And the last Hart plaintiff's
18 exhibit is Plaintiffs' 153, titled Biocompatibility Risk
19 Assessment.

20 MR. COMBS: No objection.

21 THE CLERK: Thank you.

22 MR. COMBS: The next group of exhibits is going
23 to be the exhibits related to Dr. Chen's video
24 deposition. And, in regard to this group of the exhibits,
25 I want to just rely on what we placed on the record,

1 because we actually had a sidebar and discussed those.
2 So, Mr. Cartmell was here with me at that time, and we
3 discussed what the agreements of parties were that for the
4 placement of the exhibits.

5 And I'll be glad to look at them for form as he is
6 handing them to me.

7 And we're handing the court reporter Exhibit 690,
8 which is the redacted.

9 MR. FAES: The next one is going to be 176.

10 MR. COMBS: I just want to see the redaction on
11 that one.

12 Okay, yeah, that's 686.

13 THE CLERK: And we need 176.

14 MR. FAES: Here's 176.

15 MR. COMBS: Exhibit 700 is a two-page document
16 that's Bates stamped FMESH 04097335, FMESH 04097336, and
17 Mr. Faes can just provide a copy of that at the end of the
18 lunch break in the course of that document.

19 THE CLERK: Okay.

20 MR. FAES: And the only other one I had is 969,
21 we said last night, was already in, but I don't see it on
22 the list.

23 MR. COMBS: I believe it was cut from your part
24 of the --

25 MR. FAES: I'd like to admit it, if we can.

1 MR. COMBS: Show me the document, because I
2 think it's -- it's been admitted.

3 MR. FAES: I don't believe it has. I know we
4 all said that last night, but I just checked her exhibit
5 list, and it's not on there. And it's about to be offered
6 *in camera*, as well.

7 MR. COMBS: Just -- we can go off the record
8 for a second.

9 (Off the record discussion.)

10 MR. COMBS: Okay, in regard to Exhibit 969,
11 frankly, I'm not sure whether it was admitted through Chen
12 or not, but it will be admitted with other witnesses. I
13 just don't remember.

14 THE CLERK: So, no objection to this?

15 MR. COMBS: We don't object to it. It's going
16 to be discussed with other witnesses.

17 THE CLERK: Okay. All right.

18 MR. FAES: That's everything for now.

19 THE CLERK: Okay. Thank you.

20 BENCH CONFERENCE CONCLUDED.

21 (Luncheon Recess.)

22

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25

AFTERNOON SESSION

(Out of the presence and hearing of the jury:)

THE COURT: Good afternoon. The Court will do some housekeeping.

Plaintiff's Exhibit Number 1963 is marked and admitted.

6 Plaintiff's Exhibit 1965 is marked and admitted. 1966 is
7 marked and admitted. 1971 is marked and admitted. 1970 is
8 marked and admitted. 858 is marked and admitted. 1885 is
9 simply marked. 93 is marked and admitted. 1669 is marked and
10 admitted. 690 is marked. 686 is marked. 176 is marked. 700
11 is marked. 1256 is marked and admitted. 1297 is marked and
12 admitted. 759 is marked and admitted. 153 is marked and
13 admitted. 969 is marked and admitted.

14 I'm advised that we have a very kind group of lawyers and
15 parties in this case who have agreed to equally chip in and
16 buy lunch for the jury. I think that's awful nice of you all.
17 I want to thank you. If it's all right with you, I'm just
18 going to tell them the parties have decided to buy their
19 lunch, you know.

20 MS. JONES: That would be fine, Your Honor, if you'd
21 tell them that I wanted to buy them a really good lunch.

22 MR. CARTMELL: With dessert.

23 MS. JONES: And they have --

24 MR. CARTMELL: She said McDonald's.

25 THE COURT: All right. Would you bring them in,

1 please.

2 MR. ANDERSON: Your Honor --

3 THE COURT: Yes, sir.

4 MR. ANDERSON: -- excuse me. After the next video
5 is played -- I think it's about 45 minutes -- we may need a
6 few minutes to get a few things set.

7 THE COURT: Okay.

8 MR. ANDERSON: So I don't know if that's jury time.

9 THE COURT: That will work out just fine.

10 MR. THOMAS: Your Honor, after the next video and
11 before that witness, I'm going to need a few minutes with you.

12 THE COURT: That's fine. Just remind me.

13 (Jury In)

14 THE COURT: You may be seated. Thank you.

15 Good afternoon, ladies and gentlemen. After talking to
16 you about the stinginess of your government with regard to
17 lunch tomorrow, the parties volunteered equally to buy your
18 lunch. So tomorrow they will equally treat you to lunch, and
19 I'm not chipping in anything. So it's very nice.

20 Now, we also are going to watch the weather close so that
21 we see if we need to let you out early tomorrow afternoon.
22 Right now, it looks like the temperature is going to get up to
23 40 or thereabouts around noon tomorrow and the roads should be
24 clear going home. But we'll keep a close eye on it, and if it
25 looks like we've got a problem, we'll quit a little early

1 tomorrow. But don't count on it, okay?

2 All right. Are you squared away for tonight? Everybody?

3 A JUROR: Not sure yet.

4 THE COURT: Not sure yet? Okay. Well, work with
5 Tracy on it and we'll see how it works out. My weather
6 forecasting yesterday wasn't that good, so I hesitate to do it
7 again, but it's warming up right now. And if it stops
8 snowing, it shouldn't take very long to have clear roads. So
9 we'll see.

10 We're in the middle of a videotaped deposition. We'll
11 resume where we left off. Counsel?

12 MR. CARTMELL: Thank you, Your Honor.

13 THE COURT: I should say testimony.

14 MR. CARTMELL: That's the end of the plaintiff's
15 presentation of Gene Kammerer.

16 THE COURT: Do the defendants have cross-
17 examination?

18 MR. COMBS: We do, Judge, and it's being queued up.

19 (The video of Gene Kammerer was resumed.)

20 MR. COMBS: Your Honor, that's the end of the
21 defense questions.

22 THE COURT: All right. Call your next witness.

23 MR. THOMAS: Your Honor, can we have a few minutes
24 before the next witness, please?

25 THE COURT: Yes.

1 MR. THOMAS: Thank you, Your Honor.

2 SIDEBAR CONFERENCE

3 MR. THOMAS: Your Honor, I understand the plaintiffs
4 are about to call Dr. Uwe Klinge to testify in the case. Dr.
5 Klinge prepared an 80-some page report and was deposed for two
6 days in Aachen, Germany, and I have his report.

7 I also have the testimony of Dr. Klosterhalfen, and Dr.
8 Klosterhalfen in his testimony covered almost the entire scope
9 of Dr. Klinge's report. I have for the Court the Dr.
10 Klosterhalfen deposition with the tabs in the area where he
11 covered the scope of the questions by Dr. Klinge. I have a
12 list, an index of those portions where the testimony was
13 covered.

14 The numbered categories, there are the categories which
15 appear in the Klinge report in the initial beginning. He
16 lists the categories of testimony where he is going to offer
17 testimony. What we did is we went through the Klosterhalfen
18 deposition and identified those places where Dr. Klosterhalfen
19 gave expert testimony, including ultimate opinion questions in
20 the areas that are identified there, and I noted the page line
21 where it occurred.

22 When I prepared that, I did not have the as-read copy of
23 the Klosterhalfen deposition. And I've since learned that the
24 deposition ceases at 10615. So the entries on there that
25 relate to chronic foreign body reaction, which is number one,

1 and the last one, is an alternative design, were not covered
2 in the direct.

3 So it's Ethicon's position that all of those areas have
4 been covered by Dr. Klosterhalfen. Any further testimony by
5 Dr. Klinge in that regard would be cumulative.

6 I also note rulings by the Court at the top on the
7 *Daubert* issues. The Court ruled in those three areas of the
8 *Daubert* issues. I see that Dr. Klosterhalfen has brought a
9 microscope with him. It appears that Dr. Klosterhalfen is
10 going to read slides and describe the results of the slides to
11 the jury.

12 I understood from the Court's *Daubert* ruling when you
13 ruled that the basis of his opinions for his pathology
14 opinions were unreliable, that there were no pathology
15 opinions to be offered in that regard. What I want to know is
16 the scope of the testimony of Dr. Klinge so I don't jump up
17 and down the whole time if the Court tells me he is or is not
18 going to be permitted to testify in these areas where he's
19 been precluded or there's been cumulative testimony from Dr.
20 Klosterhalfen.

21 MR. ANDERSON: First of all, I'm just now getting
22 this stack of documents that I would need more time to respond
23 to. That's one.

24 Secondly, Dr. Klosterhalfen gave numerous fact witness
25 opinions. And so at this point we're taking counsel's word

1 for it this is what it shows. If something would be
2 precluded, we would want an opportunity to counter that.

3 Third, when Your Honor addressed the *Daubert* opinions
4 regarding pathology, Ethicon was relating to the explants that
5 were not from Miss Lewis. So he brought his microscope today
6 in order to specifically address Miss Lewis's pathology. I
7 saw nothing in your order regarding that. It wasn't
8 specified. And so I would ask that this man who's flown from
9 Germany be allowed to testify today.

10 We certainly don't want to provide cumulative things, but
11 he was there from the beginning and he came here to testify
12 and we're going to try to limit him as much as we can, but he
13 does have a lot for the judge and jury to hear. He has to lay
14 a foundation for how he could give the pathology opinions
15 today and his 20 years' worth of research.

16 MR. THOMAS: Your order specifically excluded the 22
17 explants.

18 THE COURT: I take --

19 MR. THOMAS: They're on the back of his report. And
20 Mrs. Lewis is one of the 22 that was excluded.

21 THE COURT: Go ahead.

22 MR. THOMAS: The basis for his opinion, because he's
23 not a medical doctor -- he's not a pathologist. The basis of
24 his opinion where he purports to be a surgeon and a
25 histologist and transfer that knowledge into the

1 qualifications to read human pathology is reliance on the
2 explants during -- and the other 22 explants that are -- that
3 he reviewed. So that's the basis of his opinion where he
4 would give human pathology opinions. And I think that's what
5 you exclude.

6 THE COURT: I did not find a reliable basis for him
7 to testify regarding the explants basically because the manner
8 in which they were selected didn't seem to me to be a
9 sufficient foundation such for an expert opinion. I will
10 certainly let counsel attempt to qualify him to testify about
11 this woman's tissues. If he qualifies, fine. If he doesn't,
12 you can object and I'll rule on it.

13 What I would ask counsel to do is let's just let the jury
14 have a few-minute break, and go over it, try to avoid the
15 cumulative stuff. The areas where Dr. Klosterhalfen was
16 incomplete or was testifying as to facts, I will allow this
17 witness to duplicate to some extent. But there are areas, if
18 this is correct, where it's absolutely duplicative. So why
19 don't we take some time and look and see what you can do and
20 then we'll put him on the stand.

21 MR. ANDERSON: Give me a few minutes and I'll try to
22 do that.

23 THE COURT: Fifteen?

24 MR. ANDERSON: Fifteen will be great.

25 END OF SIDEBAR CONFERENCE

1 THE COURT: Good news and good news. First of all,
2 the clerk's office has heard that I've been talking about how
3 stingy the federal government is, and they've approved a hotel
4 for the night for all of you, and meals obviously that go with
5 it.

6 Secondly, we need to take an early break for the
7 afternoon. So we'll take a 15-minute break at this time.

8 Please do not discuss the case. Don't do any of those
9 other things I've told you repeatedly not to do. I'll call
10 you back. Court is in recess.

11 (Recess)

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1 (In open court following the recess. The jury is
2 present.)

3 THE COURT: Be seated. Thank you.

4 All right, counsel.

5 MR. ANDERSON: Yes, your Honor. Plaintiffs
6 call by video Ethicon preclinical scientist in research
7 and development, Joerg Holste.

8 (The videotaped deposition of Joerg Holste was
9 played.)

10 MR. COMBS: Let's stop.

11 (Mr. Combs and Mr. Cartmell conferring off the
12 record.)

13 MR. CARTMELL: Yes, that's the end of the
14 plaintiffs' version. We're going to go to the defendants.

15 THE COURT: All right.

16 MR. COMBS: Judge, the defense will have a
17 brief redirect, but it's going to take a few seconds to
18 cue it up.

19 THE COURT: Sure.

20 MR. COMBS: Thank you.

21 THE COURT: I like any part that begins with
22 the word "brief."

23 MR. COMBS: It will be brief.

24 (Videotaped deposition of Dr. Holste continues.)

25 MR. COMBS: Judge Goodwin, that ends the

1 questions by the defense.

2 THE COURT: All right, is that the end of this
3 videotape?

4 MR. ANDERSON: Yes, your Honor.

5 THE COURT: All right, call your next witness

6 MR. ANDERSON: Yes, your Honor. The plaintiffs
7 call Dr. Uwe Klinge.

8 UWE KLINGE, PLAINTIFFS' WITNESS, SWORN

9 DIRECT EXAMINATION

10 BY MR. ANDERSON:

11 Q. Good afternoon, Dr. Klinge.

12 A. Good afternoon.

13 Q. State your name, please, for the jury.

14 A. My name is Uwe Klinge.

15 Q. And where are you from, Dr. Klinge?

16 A. I'm coming from Germany and I'm -- yeah, I'm living in
17 Aachen.

18 Q. And what is your profession?

19 A. I'm a medical doctor. I'm a surgeon, mainly a surgeon
20 of diseases in the abdominal cavity and the abdominal
21 wall. And I'm a scientist as an employee of the
22 university, and the focus is biomaterials, and
23 particularly biomaterials in soft tissue that are textile
24 implants, and the evaluation of the functional
25 consequences and basic pathology consequences of this.

1 MR. ANDERSON: May I approach, your Honor?

2 THE COURT: You may.

3 BY MR. ANDERSON:

4 Q. Dr. Klingen, I'm showing you what has been marked as
5 Plaintiff's Exhibit 1-A.

6 Doctor, is exhibit 1-A a copy of your curriculum
7 vitae?

8 A. That's true.

9 Q. Briefly, if you would, just tell the jury a little bit
10 about your professional career from medical school to the
11 present?

12 A. When I finished medical school, which I went to
13 Aachen, to the medical school at Aachen, I started as a
14 surgical resident at the university hospital at the
15 surgical department there, and I was --

16 Q. Just a second. Talk just a little bit slower for the
17 court reporter and for the jury, okay?

18 A. Sorry. So, in 1985, I started as a surgical resident
19 at the surgical department of the university clinic, and
20 since then I was trained as a surgeon and -- yeah -- so,
21 finally, that I can finish my education as a surgeon at
22 this department and were able to -- to do all of the major
23 operations in the abdominal cavity there.

24 Q. And did there come a point in time when you
25 transitioned out of hernia surgery on a day in and day out

1 basis?

2 A. I --

3 Q. I'm sorry. Did there come a time when you
4 transitioned out of hernia surgery?

5 A. I don't understand.

6 Q. I'm sorry. English is not your first language, and --

7 A. No, sir.

8 Q. -- you speak German. Let me try a little better. I
9 apologize.

10 What did you -- after practicing as a hernia
11 surgeon, what else have you done in your professional
12 career?

13 A. So the -- the main work was working as a visceral
14 surgeon.

15 Q. And what is a visceral surgeon?

16 A. They work with diseases of the intestine and the
17 abdominal cavity, or the organs in there. So, I'd treat
18 all these diseases and the diseases of the abdominal
19 wall. That is, all kinds of hernias belong to this field
20 of surgery. So this has been the focus of my surgical
21 work there. And besides, we made a lot of scientific
22 work, as I said, with a focus on surgical meshes.

23 Q. And in terms of that work on the biomaterial science
24 on of surgical meshes, approximately how long have you
25 been studying that, Doctor?

1 A. We started to work scientifically on the meshes when
2 they -- in the beginning of the nineties, and we are not
3 finished yet. We are still working on this topic.

4 Q. As part of that biomaterials science work, have you
5 reviewed pathology slides or histopathology slides?

6 A. Yes. It was quite clear from the beginning that we
7 have to look very careful to the -- to the tissue response
8 to this material, and, therefore, we -- I had to learn to
9 evaluate the tissue response to these textile implants.

10 Myself and -- at the beginning, when we started to
11 do so, there hardly was any good way to analyze the tissue
12 response, and, therefore, together with Klosterhalfen, we
13 had to establish a lot of criteria to define whether it's
14 a good or a bad or a difficult tissue reaction to the
15 material.

16 Q. By the material, you mean surgical meshes for the
17 body?

18 A. Surgical meshes in the body, yes.

19 Q. So, how did you go about getting this training to
20 review pathology slides with Dr. Klosterhalfen beginning
21 20 years ago, 30 years ago?

22 A. Well, actually, we have been sitting many times
23 together and looking together to the explants that we
24 made, and because we used a lot of modifications where we
25 clearly knew what has been the modification, so then we

1 learned what is -- what is a change of the tissue reaction
2 when you apply or when you use a material with a certain
3 modification.

4 And thereby we learned what is relevant, what's
5 predicts the outcome of the mesh materials.

6 Q. When you're talking about this prediction of the
7 outcome of materials by looking at slides and
8 histopathology, just explain for the jury what
9 histopathology is?

10 A. It's the pathology -- mainly is the analysis of the
11 tissue on the microscopical level. So, it's usually
12 the -- the properties of the tissues that you cannot see
13 with the naked eyes.

14 Q. When did you first start learning about pathology or
15 training, based upon your education and background?

16 A. Pathology and histology is an essential part of the
17 medical school, so, therefore, it started it. Then, later
18 on, there are regular meetings with the pathology at
19 almost all diseases that we treat surgically, and mainly
20 for all types of cancer. So, we had regular meetings
21 together with the pathologists to discuss these
22 histological findings.

23 And then, yeah, as I said, we learned it by our
24 studies, preclinical studies, and by the analysis of
25 explanted meshes from humans that we started to collect to

1 learn about it. And so, I looked to many, many of these
2 explanted meshes.

3 Q. So you trained with Dr. Klosterhalfen and the other
4 pathologists about reviewing histopathology slides?

5 A. Yes, yes.

6 Q. Over these last 20 years, approximately how many of
7 these histopathology slides have you, yourself, reviewed,
8 analyzed and interpreted of surgical meshes explanted from
9 the human body?

10 A. I only can roughly estimate it. We don't have a
11 counter there. But it is at least 20,000 or more.

12 Q. Who has relied on your pathology work over those 20
13 years and in your review of histopathological slides?

14 A. A lot of our studies include the histological analysis
15 of these results. So, every -- so everyone who read these
16 articles, he has to -- or he would -- relied on the
17 results of these analyses.

18 Q. I noticed in your CV -- let me see if I can ask it
19 this way -- it shows that you've written some findings in
20 your CV?

21 A. Yes. We published everything. We want to publish all
22 of our findings at the university. That is, our -- our
23 main task is to educate and to provide our findings to the
24 public.

25 Q. How many publications in the scientific literature

1 have you written, Dr. Klinge?

2 A. It's more than 200.

3 Q. And how many times has your work been cited by other
4 scientists and surgeons in the scientific literature?

5 A. It's actually more than 2,000 times.

6 Q. Approximately how many of those scientific
7 publications of yours relate to mesh for the abdomen or
8 the pelvis?

9 A. For the purpose of meshes, it's more than a hundred.

10 So, half of them.

11 Q. And in those publications, how many times were you the
12 scientist that was responsible solely for the
13 histopathology of a tissue reaction in explanted meshes?

14 A. In about 50.

15 Q. You talked a little bit about the University of
16 Aachen. Is that where you're still currently employed,
17 sir?

18 A. Yes. Yes.

19 Q. And in terms of textile research, how does the
20 University of Aachen rank in terms of textile research
21 facilities in the entire world?

22 A. Their technical university is one of the few technical
23 universities which has a combination of a medical faculty
24 and the textile engineering, and the textile university is
25 one of the top locations in Germany and for the -- or for

1 the engineering of the machines of the textile. It is
2 maybe one of the top faculties of the world.

3 Q. Is there anyone that you're aware of, other than you
4 and Dr. Klosterhalfen, who has studied surgical meshes in
5 the world over the last 20 years?

6 A. No, I don't know any, and I don't know any who has our
7 combination of combining engineers and pathology and
8 surgeons.

9 MR. ANDERSON: May I approach, your Honor?

10 THE COURT: You may.

11 BY MR. ANDERSON:

12 Q. Doctor, at my request, did you prepare an expert --
13 well, three expert reports in this case?

14 A. I did.

15 Q. And I would like to identify them as Plaintiff's
16 Exhibit 1, 1-B and 1-C.

17 MR. ANDERSON: Your Honor, I'd like to offer
18 1-A, 1 -- I'm sorry, 1, 1-A, 1-B and 1-C, please.

19 THE COURT: Is that four exhibits or just
20 three?

21 MR. ANDERSON: It's the CV and three reports.

22 MR. THOMAS: Your Honor, I have no objection to
23 the CV, but I do object to the reports being received into
24 evidence.

25 THE COURT: All right, I'll admit the CV. I

1 don't think sufficient foundation has been laid for the
2 others.

3 MR. ANDERSON: Nor did I intend to, your Honor.

4 Thank you.

5 BY MR. ANDERSON:

6 Q. In writing your report and in coming to the opinions
7 that we'll address with the jury today, did I ask you to
8 review internal Ethicon documents?

9 A. Yes.

10 Q. Approximately how many pages of Ethicon documents have
11 you reviewed in the course of your work in this case, sir?

12 A. More than a thousand.

13 Q. And have I asked you to review depositions?

14 A. Yes.

15 Q. Have you reviewed internal Ethicon depositions at my
16 request?

17 A. I reviewed about a dozen of depositions.

18 Q. And have you reviewed scientific literature both
19 before this case and during the pendency of this case that
20 relates to the issues of textile meshes and polypropylene
21 meshes in the human tissue?

22 A. That is part of my daily work, but, particularly for
23 this case, I intensified some research through some
24 specific issues.

25 Q. Dr. Klingen, what is Prolene mesh; the Prolene mesh

1 that's used in the TVT?

2 A. Prolene mesh is a textile construction with a double
3 filament. It is, in comparison to others, very heavy.
4 That means that it has a considerable amount of material
5 in comparison to others. It is done of -- or it is
6 constructed -- the polymer is the polypropylene.

7 Polypropylene is a plastic material that is used -- widely
8 used in our daily life. So, all -- most of the plastic
9 bags are made of polypropylene.

10 Q. And do any of the studies that we've talked about in
11 the publications, the hundreds of publications in your CV,
12 do any of those involve research on Ethicon's Prolene
13 mesh?

14 A. Most of our preclinical studies include the use of the
15 Prolene mesh as a reference of a -- yeah, so-called heavy-
16 weight small-pore meshes, or mesh material of the most
17 intense tissue reaction. And, therefore, we used it in
18 most of -- almost all of our preclinical studies.

19 Q. Going back to what time period did you first start
20 looking at and analyzing the Prolene hernia mesh that is
21 also the Prolene mesh in TVT?

22 A. The first clinical -- or there is -- the first
23 experiments we did to characterize the response to some
24 currently -- at that time currently available meshes, they
25 started in 1994. There we took some mesh materials that

1 are available on the market at that time, and we placed it
2 in tissue, and then we tried to identify the parameters
3 that are decisive for characterization of the biological
4 response to these different materials.

5 Q. The jury has just heard from a Joerg Holste, an
6 Ethicon employee. Are you familiar with Dr. Holste?

7 A. Yeah, I know him good.

8 Q. How long have you been working with Dr. Holste at
9 Ethicon?

10 A. I've seen him the first time -- or the closer
11 collaboration, it started in 1994.

12 Q. Explain to the jury just briefly about your
13 collaboration and consulting work with Ethicon dating back
14 to the nineties?

15 A. Beginning with this focus on the meshes, it started in
16 the beginning of the nineties, because at that time there
17 came up some surgical procedures that used these mesh
18 materials, and there was an intense discussion among the
19 surgeons whether really to use these meshes or still using
20 only suture materials. And, in this discussion, there
21 are -- was the, or we all felt that it is necessary to
22 understand little bit more about the meshes, in
23 particularly, as we have to make some revision operations
24 of these mesh materials, and we saw that there are some
25 complications, though we implanted them in a correct way.

1 And, to understand this, we said we have to learn a
2 lot more about these materials, and, in particularly, we
3 hoped that we can reduce the amount of the material and,
4 therefore, make it more safe.

5 That was the basic idea why we started to think in
6 this direction, and we had the opportunity at the
7 university to build up a scientific research group for the
8 studying of biomaterials and meshes, in particularly. Now
9 we got a grant so that we could do it. But when you want
10 to study meshes, you need specific modifications of these
11 meshes, and you are not able -- in surgery, we weren't
12 able to prepare these modifications. So, you have to
13 contact the manufacturer. You have to work with a
14 manufacturer who provides the filaments and who provides
15 the mesh materials, and then together you can create these
16 experimentally implants and then making your studies with
17 this.

18 And the manufacturer working for these projects,
19 that has been Ethicon from the beginning.

20 Q. So, in this collaboration between your group and the
21 biomaterials research group in Aachen in this
22 collaboration with Ethicon, were you able to actually
23 reduce the material and develop a new product?

24 A. That -- that was finally the end of the first phase
25 that we -- as Joerg Holste had turned it already; that we

1 could reduce the amount of the material to one-third, and
2 that we can -- could demonstrate in multiple studies, and,
3 later on, even in clinical studies that the reduction in
4 the amount of the material improves the clinical outcome
5 and reduces the risk for the patient.

6 Q. And what was the name of that product that was
7 developed in collaboration between you and Ethicon in the
8 nineties?

9 A. This first really large pore meshes has been -- was
10 named as Vypro. It was a combination of polypropylene and
11 an absorbable product.

12 Q. And after the development of Vypro, did Ethicon begin
13 to sell that and other light-weight meshes for hernia
14 repair?

15 A. After the development of the Vypro, the subsequent
16 mesh development by Ethicon was in the direction of -- of
17 these large-pore mesh constructions. Successor is --
18 successor has been the UltraPro, and even today, with the
19 Physiomesh, they provided --

20 Q. So, was this an evolution from Prolene to Vypro to
21 UltraPro to Physiomesh in terms of weight and pore size?

22 A. Yeah. We -- we could show in -- with our studies that
23 it was an advantage for the patient to reduce the amount
24 of the material, and this principle -- this is a
25 principle. This principle is still used in many of the

1 products.

2 Q. You're familiar with the old construction 6 mil
3 Prolene that is used in TVT products; correct?

4 A. Yes.

5 Q. After Ethicon went to selling Vypro and then UltraPro
6 as lighter-weight large-pore meshes for hernia repair, did
7 it stop selling the old construction 6 mil hernia repair
8 mesh?

9 A. So far I know that the selling of the Prolene
10 continued, but the Prolene -- the old Prolene mesh
11 changed -- or got a little bit some changes in the textile
12 construction. But it's still the prototype of a heavy-
13 weight mesh.

14 Q. What year did Ethicon stop selling the Prolene 6 mil
15 old construction for hernia patients?

16 A. Pardon?

17 Q. What year did Ethicon stop selling -- strike that.

18 Did you review some internal deposition testimony of
19 a -- of Ethicon employees regarding it?

20 A. So far I remember, in 2001 the old Prolene was
21 replaced by a -- a new version.

22 Q. And you mentioned UltraPro as a light-weight large-
23 pore mesh by Ethicon. How much larger were the pores and
24 how much lighter was the weight than the old construction
25 Prolene?

1 A. It's another world. It is the -- the pore size of
2 UltraPro is more than 3 millimeters, whereas the pore size
3 of the Prolene is less than 1 millimeter. So, it's
4 considerably significantly more open.

5 Q. And what about the weight? How does the weight
6 compare with their UltraPro mesh to their old construction
7 Prolene?

8 A. The weight is -- if you're -- it has a part of
9 absorbable material, and this is absorbed. It is
10 one-third in comparison to the Prolene mesh.

11 Q. After your review of the materials, did you come to an
12 understanding as to whether Ethicon uses the UltraPro mesh
13 in another part of the body?

14 A. Yes.

15 Q. What part of the body is that?

16 A. UltraPro of a large-pore conception was used in -- in
17 meshes for the repair of prolapse.

18 Q. Did you say prolapse?

19 A. Prolapse.

20 Q. Okay. So, Ethicon sold a light-weight large-pore mesh
21 for hernia, a light-weight large-pore mesh for prolapse.
22 Does it sell a light-weight large-pore mesh for stress
23 urinary incontinence in women's vaginas?

24 A. No.

25 Q. After your review and your study over the last 20

1 years of surgical meshes and surgical implants and
2 explants and your review of all of the literature and your
3 background, training and experience, have you ever been
4 able to come to any understanding as to why Ethicon
5 continues to sell a heavy-weight small-pore --

6 (Mr. Thomas rising.)

7 THE COURT: Sustained.

8 BY MR. ANDERSON:

9 Q. While you were a consultant at Ethicon did you speak
10 at conferences at their request?

11 A. Yes, several times.

12 Q. At what point in time did your consulting
13 relationship, if you will, stop with Ethicon?

14 A. The collaboration or the working together with
15 Ethicon, it definitely or finally stopped in 2012. We
16 have from 1994 to the beginning of 2004, '5, we have this
17 development of this very intensive joint development of
18 meshes, the discussion of the results. Later on we had
19 ongoing projects Aachen. I think they finished in 2009.

20 We had regularly meetings there till 2009. That's --

21 Q. Have you been asked by Ethicon to speak at conferences
22 that they sponsored regarding biomaterials science and
23 pathology of surgical meshes used in the pelvic floor?

24 A. Yes.

25 Q. And have you been asked by Ethicon to speak at

1 conferences urogynecologists, gynecologists and urologists
2 about pelvic-floor meshes either for prolapse or SUI?

3 A. Yes.

4 Q. In the course of your work, where you've looked at --
5 you mentioned that you'd looked at animal explants. Have
6 you also looked at explants from humans regarding Prolene?

7 A. Yes. We know from the beginning that animal
8 experiments have -- or have important limitations, and
9 that for -- that we have to edit or we have to look at
10 what happens in the humans. And the only occasion that we
11 had --

12 MR. THOMAS: Your Honor?

13 THE COURT: I know the limitations I've placed
14 on this. I assume counsel does, too. As long as this
15 answer stays as general as I it has so far, we're fine.
16 If it goes much further, we aren't.

17 MR. ANDERSON: Thank you, your Honor.

18 THE COURT: Okay.

19 BY MR. ANDERSON:

20 Q. Have you personally analyzed and done the
21 histopathological analysis of hernia explant meshes with
22 Prolene in them?

23 A. Yes.

24 Q. Is that part of your work at the biomaterials research
25 group in Aachen University?

1 A. Yes.

2 Q. And have you also reviewed pelvic-floor meshes and the
3 tissue response to pelvic-floor meshes as part of your
4 work at Aachen University?

5 A. Yes.

6 Q. Approximately how many tissue samples or explants have
7 you reviewed either for hernia meshes or pelvic-floor
8 meshes as part of your work at Aachen University?

9 A. We have collected at our university 500 hernia
10 meshes -- hernia meshes, and I've reviewed some of the
11 meshes that are collected in Duren by Prof. Klosterhalfen,
12 as well.

13 MR. THOMAS: Your Honor?

14 THE COURT: Sustained. The jury will disregard
15 the last question and answer.

16 MR. ANDERSON: May I approach, your Honor?

17 THE COURT: Sure, but I did rule on this.

18 SIDEBAR CONFERENCE:

19 THE COURT: All right, sir.

20 MR. ANDERSON: Your Honor, this is what we
21 sought to clarify with our motion for clarification with
22 your Honor. As part of Dr. Klinge's work, he has
23 published extensively on the explant database that he has
24 maintained at his university and with Duren. He's
25 published in the worldwide reviewed literature, and he is

1 one of the persons in charge of the European Hernia
2 Society's explant database.

3 What I'm trying to do here, sir, is to ask your
4 Honor if -- to lay a foundation for the fact that he's
5 reviewed pathology slides, 25,000 of them, over 20 years.

6 THE COURT: He said that.

7 MR. ANDERSON: And I want to make sure that
8 I've laid the foundation so he can talk about Ms. Carolyn
9 Lewis' explants. But I can't do that if he can't talk
10 about at lease that he has reviewed these over the course
11 of his career.

12 MR. THOMAS: Your Honor?

13 THE COURT: Yes.

14 MR. THOMAS: His deposition testimony is very
15 clear that when he has collected hernia explants at the
16 University of Aachen he has not collected and has decided
17 not to collect explants from the pelvic floor. So, his
18 expertise in this regard is clearly related only to hernia
19 explants and not to pelvic floor meshes that he's
20 collected himself.

21 I would suggest to the Court that selection bias
22 exists for any other mesh collections that we've already
23 talked about.

24 THE COURT: And on your, I guess -- I forget
25 how you styled the motion for me to think it over again.

1 MR. ANDERSON: Yes, sir.

2 THE COURT: I actually ruled on that, as well.

3 There is no question that this guy has looked at meshes of
4 different kinds through microscope. You brought that out.

5 MR. ANDERSON: Okay.

6 THE COURT: He's looked at explants of various
7 kinds, and you've brought that out. Now, whether he's
8 qualified to render some opinion about Ms. Lewis' explant,
9 I don't know yet.

10 MR. ANDERSON: That's why I was trying to ask
11 if he had ever done histopathological analyses on the
12 meshes that have been explanted from the pelvic floor. I
13 can't lay that foundation if your Honor won't let me ask
14 it.

15 And I saw that you didn't like my response, so I was
16 going to -- I wanted to ask for my own sidebar just
17 because I want some clarification. I don't want your
18 Honor to be upset at me.

19 THE COURT: No, no, no, I'll never be upset.
20 Mr. Anderson, you can be assured I won't be upset with any
21 of you.

22 MR. ANDERSON: You can get there, though. And
23 I want -- I want help. I don't know how you want me to do
24 that.

25 THE COURT: Well, he's not a pathologist, but

1 he is a surgeon. He has testified that he has had
2 extensive experience and published peer-reviewed articles
3 involving conclusions he drew about histology.

4 So, I don't know which of those articles -- he said
5 about 50 of them -- the histological opinions were solely
6 his.

7 MR. ANDERSON: That's right.

8 THE COURT: And if he has 50 peer-reviewed
9 articles with histological conclusions, and you can tie
10 that -- I'm not trying to tell you how to try your case --
11 if you can tie that to him looking at Mrs. Lewis' SUI mesh
12 somehow -- I don't know what these articles are -- and
13 maybe you can get there. That's about the best I can do
14 for you.

15 MR. ANDERSON: I tried to get there, your
16 Honor, but I -- I will tie it more to the publications
17 than to looking at the explanted pelvic floor meshes in
18 Duren. Is that --

19 THE COURT: Well, as I understand it, unless
20 you lay a further foundation, I'm not sure that -- as I
21 pointed out in my ruling, I don't know what -- there was
22 no indication how the meshes that he collected and studied
23 were chosen nor how he formed opinions based upon that
24 particular collection that were reliable. So, there
25 wasn't enough information from which I could conclude that

1 it wasn't junk science.

2 The Supreme Court hasn't been extraordinarily
3 helpful with Daubert, and, frankly, beyond the fact that
4 the Fourth Circuit is pretty generous to doctors on
5 differential diagnosis, nor have they.

6 So, I just have to do my own best shot at this. And
7 I've told you all, I'm going to tell you now, take a shot
8 and we'll see how it goes.

9 MR. ANDERSON: Thank you, your Honor.

10 END OF SIDEBAR CONFERENCE.

11 BY MR. ANDERSON:

12 Q. Dr. Klingen, as part of these publications that you
13 mentioned in which you were the pathologist or
14 histopathologist reviewing slides, did some of those
15 include your review of explanted meshes from women's
16 pelvic floors?

17 A. Yes.

18 Q. Is that something that you have done over the course
19 of the last 15 years, is look at explanted meshes from the
20 pelvic floor and published on them?

21 A. Yes.

22 Q. I show you what is marked as Plaintiffs' Exhibit 1993.

23 MR. ANDERSON: If I may approach, your Honor?

24 THE COURT: You may.

25 BY MR. ANDERSON:

1 Q. And I'd also like to show you Exhibit 1998 at the same
2 time.

3 THE COURT: What was the first one, I'm sorry?

4 MR. ANDERSON: 1993, sir.

5 THE COURT: All right.

6 BY MR. ANDERSON:

7 Q. I'm showing you what we've marked as Plaintiffs' 1993
8 and 1998. Are those documents that you had within your
9 files that you produced in this litigation?

10 A. That's true.

11 Q. Okay.

12 MR. ANDERSON: Your Honor, if we could show
13 1993 and 1998?

14 MR. THOMAS: Your Honor, they're in German. I
15 don't know what they are. I don't think the witness has
16 identified them yet, other than being documents from his
17 file.

18 MR. ANDERSON: Okay.

19 BY MR. ANDERSON:

20 Q. In 1993, what's the title of that?

21 A. The title of this symposium that took part in Hamburg
22 in 2007, the title was Pelvic Floor Mesh Forum.

23 Q. What does it say to the upper left of this Pelvic
24 Floor Mesh Forum?

25 A. At the upper left on this page there is written

1 "Ethicon women's health and urology."

2 Q. Were you an invited lecturer at the Ethicon women's
3 health and urology at Ethicon's facilities?

4 A. Yes. I was asked to give an overview of the
5 scientific basis and the clinical evidence.

6 Q. And were you invited as a speaker at Ethicon to speak
7 urogynecologists, gynecologists and urologists about, in
8 part, the histology of pelvic-floor meshes?

9 A. Yes, that's correct.

10 Q. And is this presentation something that you prepared
11 at Ethicon's request to present at Ethicon to urologists,
12 gynecologists and urologists?

13 A. Yes.

14 MR. ANDERSON: Your Honor, I would seek to
15 admit 1993 and 1998.

16 MR. THOMAS: Your Honor, I have no objection
17 based on foundation. I can't read it.

18 MR. ANDERSON: And if you would allow me --

19 THE COURT: Let me see you both at sidebar for
20 a minute, because I have another matter I need to mention.

21 SIDEBAR CONFERENCE:

22 THE COURT: Okay, this still might be helpful.
23 One of the main things that I said is that Dr. Klinge did
24 not put in his report -- and put it in a footnote on page
25 11 -- although Ethicon asserts that Dr. Klinge's specific

1 causation opinion should be excluded, I said he offers
2 none that I could find. So, what I'm concerned about now,
3 is he about to offer a conclusion on specific causation
4 which was not a part of his report? So I'm just -- I
5 don't know where you're going, so --

6 MR. THOMAS: That's a big part of my concern,
7 too, as well, your Honor.

8 MR. ANDERSON: The pathology slides in his
9 report reflect Ms. Lewis' pathology. He asked --
10 Mr. Thomas asked him about that at his deposition, at his
11 two-day deposition. On the second day he asked him are
12 those Mrs. Lewis' slides. Yes, they are. And he went
13 into them extensively, and there were page after page of
14 pathology slides from Mrs. Lewis.

15 THE COURT: I understand, Mr. Anderson. Well
16 perhaps I should wait for the objection. I just want to
17 share with you my concern as to specific causation,
18 because I didn't see that he was listed as offering one.
19 They acted like he did. I agree with you, because they
20 objected to it.

21 MR. ANDERSON: Underneath each of the
22 photographs in his report, he says bridging fibrosis or
23 shrinking, and that's why I was trying to lay a
24 foundation. The fact that --

25 THE CLERK: One of the jurors needs a break

1 right now.

2 END OF SIDEBAR CONFERENCE.

3 THE COURT: Okay, we'll take a brief break.

4 Remember my other admonitions. Let's come back in about
5 five minutes.

6 (The jury withdrew.)

7 This always happens to me. I'm trying to speed
8 things up and I had the effect of just slowing it down.
9 So I'm going to let you go forward the way you want to,
10 and the objections will come or not come.

11 (Off the record discussion.)

12 SIDEBAR CONFERENCE:

13 MR. ANDERSON: If your Honor feels at this time
14 that I have not laid an appropriate foundation for him to
15 be able to speak to the pathology slides, I don't know how
16 much further I can go with trying to qualify him.

17 THE COURT: Well, I can't offer advisory
18 opinions, but you just told me about something under the
19 pictures over there --

20 MR. ANDERSON: Yes.

21 THE COURT: -- that I thought was interesting.

22 Let me be blunt, Mr. Anderson. I wouldn't give up
23 yet.

24 MR. ANDERSON: All right. Thank you, your
25 Honor. I don't want to keep beating my head against the

1 wall. I don't want to keep beating my head against the
2 wall, your Honor.

3 THE COURT: Sorry, Ms. Jones.

4 MS. JONES: Give up.

5 END OF SIDEBAR CONFERENCE.

6 THE COURT: Okay, if they're ready, we'll
7 start.

8 Is there a chance we'll get this witness done today?

9 MR. ANDERSON: Given some of the rulings that
10 we've had here earlier about nonduplicative testimony, I
11 would think that we will -- given the pathology -- end it
12 today.

13 THE COURT: All right.

14 MR. THOMAS: Pardon?

15 THE COURT: I was just trying to find out if we
16 thought we'd finish the rulings today. He thought he was
17 going to get the pathology and cross, and we'll finish
18 with him.

19 MR. THOMAS: So you're going to go solely to
20 pathology?

21 THE COURT: Makes you happy, doesn't it?

22 MR. THOMAS: I'm always --

23 THE COURT: You look happy.

24 Let's go.

25 (The jury entered the courtroom.)

1 Thank you, ladies and gentlemen. You may be seated.

2 Thank you, Doctor.

3 Mr. Anderson?

4 MR. ANDERSON: Thank you, your Honor.

5 BY MR. ANDERSON:

6 Q. Referring back to Plaintiffs' Exhibit 1, your expert
7 report, Dr. Klinge, in your expert report do you provide
8 photomicrographs of tissue samples taken from Ms. Lewis?

9 A. Yes.

10 Q. And are these the type of tissue samples that you
11 reviewed in the past and published articles on, as you
12 explained to the jury?

13 A. Yes.

14 Q. And are these the type of pathology slides of tissue
15 samples that you have presented at conferences around the
16 world?

17 A. Yes.

18 Q. And did I ask you to review different types of
19 pathology slides for purposes of offering your opinions
20 here to the jury today?

21 A. For this case, yes.

22 Q. Okay. And what different types of slides did we ask
23 you to have prepared to be able to look at the tissue
24 samples coming from Ms. Lewis?

25 A. Basically, these are two different stains. The first

1 is a staining for the cells and for the -- for the tissue
2 in between the cells, what we call the matrix, and mainly
3 this is the collagen to identify whether there is scar
4 tissue or fat tissue or other tissues. This is one
5 stain.

6 And the other stain is to look whether there are
7 some nerves that are entrapped into -- in this scar
8 tissue. And this is done because these nerves are very,
9 very small, so that you cannot identify them just by
10 looking. You need some specific markers that are specific
11 for the -- or that binds specifically to the tissue of
12 nerves.

13 And then you have an additional marker with a brown
14 color. So then you can made a marking of these nerve-like
15 structures --

16 MR. THOMAS: Your Honor?

17 THE COURT: Yes?

18 MR. THOMAS: I think he's going well past
19 foundation, if that's what we're trying to do. I object
20 to it.

21 THE COURT: I'm going to allow it. Please go
22 on.

23 MR. ANDERSON: Thank you, your Honor.

24 BY MR. ANDERSON:

25 Q. Did you bring some of those slides from Ms. Lewis here

1 today to show the jury?

2 A. Yes.

3 MR. ANDERSON: Your Honor, may he show the
4 slides from Ms. Lewis?

5 MR. THOMAS: Your Honor, I object and request
6 sidebar.

7 THE COURT: Sure, we can have a sidebar. We
8 haven't had one for awhile.

9 SIDEBAR CONFERENCE:

10 THE COURT: All right, sir.

11 MR. THOMAS: Your Honor, I object to Dr. Klinge
12 given any pathology opinions. I don't believe an adequate
13 foundation has been laid.

14 To the extent the Court is inclined to hear
15 testimony, I'd request that I be able to take the witness
16 on voir dire at this point.

17 The other thing I'd like to remind the Court, and
18 this is true, while there are pathology slides identified
19 in the report, you will find nowhere in the report where
20 Dr. Klinge says it's my opinion to a reasonable degree of
21 certainty in my field of expertise that Carolyn Lewis has
22 such-and-such a condition based upon these findings that I
23 find from the slides.

24 There are comments made about the numbered slide,
25 but nowhere in the report is there a statement by the

1 expert that there is a condition that she has suffered as
2 a result of a defect that he's found in the mesh.

3 MR. ANDERSON: She has chronic pain and
4 dyspareunia, he has identified in the slides, and that's
5 what I was trying to lay the foundation for, the
6 foundation there that the brown stain S, 100 and that's
7 found entrapped in nerves.

8 THE COURT: What is there in the report about
9 that?

10 MR. ANDERSON: It shows an entrapment -- can I
11 get the report?

12 THE COURT: Yes.

13 (Pause.)

14 All right, Mr. Anderson.

15 MR. ANDERSON: Yes. So the inflammatory slides
16 begin on page 70 of Dr. Klinge's report, and it says 40X
17 making any folded mesh and intense inflammatory reaction,
18 intense, a pronounced acute inflammation, and then I think
19 I told you confirmed the inflammatory and fibrotic tissue
20 reaction, polymer particles --

21 THE COURT: Okay.

22 MR. ANDERSON: -- etc.

23 THE COURT: I'll let you do voir dire of him if
24 you like. I'm going to let it in. But it's up to you.

25 MR. THOMAS: If that's your ruling, I'll save

1 it for cross then.

2 THE COURT: That's what I thought you'd do.

3 MR. ANDERSON: Thank you.

4 END OF SIDEBAR CONFERENCE.

5 THE COURT: All right, sir.

6 MR. ANDERSON: Thank you.

7 BY MR. ANDERSON:

8 Q. Dr. Klingen, did you bring some pathology slides from
9 Ms. Lewis that you could show to the jury here today?

10 A. Yes.

11 Q. Okay. Do you have a microscope there so that you
12 could show the jury some of the points of her slides that
13 you analyzed for me?

14 A. Yes.

15 MR. ANDERSON: Your Honor, can he put it on the
16 screen now, please?

17 THE COURT: Yes.

18 MR. ANDERSON: May I approach?

19 THE COURT: You may.

20 BY MR. ANDERSON:

21 Q. All right, will you please just explain to the jury
22 what we're looking at here in terms of Mrs. Lewis' explant
23 slides?

24 A. So, what we see here.

25 THE COURT: Hold the microphone closer, would

1 you?

2 THE WITNESS: Yes.

3 A. What you see here is a so-called HE staining of the
4 tissue. It's a very small sample, and we look through the
5 magnification of 40.

6 All these white areas here that are the areas where
7 the mesh initially has been placed there. And if you --

8 MR. ANDERSON: One second.

9 (A juror's monitor is malfunctioning. The Clerk
10 resolved the problem.)

11 THE COURT: Thank you, Robin.

12 MR. ANDERSON: Thanks, Robin.

13 THE COURT: All right.

14 A. So, this white area here, this is the area where the
15 mesh fibers has been -- or were. But these are very, very
16 thin sections, and by cutting these sections, the plastic
17 material is removed, so that you usually cannot see
18 directly, with some exceptions, the plastic material
19 itself. You just can see the tissue response around it.

20 But if you will look on look to this area or to this
21 part here, there has been the filament, and the filament
22 has a diameter of 117 microns, and this is the same
23 diameter of this hole. So, you usually see the holes
24 where the polymer fibers were.

25 Q. So, the circles to the right and to the left of the

1 screen, those would be polypropylene Prolene fibers in the
2 TVT mesh; correct?

3 A. They have been here, they were there, and here in this
4 area, and here there has been these polymer fibers.

5 Q. And please explain to the jury what the pink or the
6 red area is in between those fibers.

7 A. When the tissue -- when the plastic material is placed
8 in the tissue, then the patient or the tissue activates
9 the defense mechanism, and the first defense mechanism is
10 that a lot of cells are accumulated at the surface of
11 these materials. These are inflammatory cells, and they
12 try to -- to block the surrounding tissue from these
13 foreign-body materials.

14 That is what is said, the foreign-body reaction, the
15 inflammatory part of the foreign-body reaction. These are
16 here all these blue cells that you can see here, and --

17 Q. And what is -- I'm sorry, Dr. Klingen. What is the red
18 part in between the fibers?

19 A. The red part in between the fibers, that is scar
20 tissue. And the most prominent part of scar tissue is
21 collagen, and this is stained red.

22 Q. Based upon your work with Ethicon and your literature
23 and your 20 years of research in this area, is there a
24 greater risk for the red inflammatory reaction in the
25 tissue if the pores are a certain pore size between each

1 other?

2 MR. THOMAS: Objection, your Honor.

3 Foundation.

4 THE COURT: Give me a minute.

5 A. So --

6 THE COURT: Wait just a second.

7 MR. ANDERSON: No.

8 THE COURT: Wait just one second.

9 Overruled. You may answer.

10 BY MR. ANDERSON:

11 Q. Is there a minimum pore size between the fibers that
12 we're seeing here that will cause fibrotic bridging?

13 A. You see in this image that the entire space between
14 these filaments is filled by scar tissue. There is no
15 other -- there is no other tissue. And if you measure the
16 distance between these fibers here, you will find that
17 it's usually a very small distance.

18 So the pores here in this cross-cutting are very,
19 very small, and all this tissue around these mesh
20 materials, it's only scar tissue.

21 Q. And what does that mean for the patient when you see
22 only scar tissue in between the fibers of surgical meshes?

23 A. If the --

24 MR. THOMAS: Your Honor, I object to this.

25 THE COURT: Sustained. You need more

1 foundation for that, Mr. Anderson.

2 BY MR. ANDERSON:

3 Q. As we were talking with the jury about a few minutes
4 ago, have you, as part of your work over the last 20
5 years, treated hernia patients who have had similar
6 histopathology as what we see on the screen?

7 A. This is a typical reaction for all heavy-weight small-
8 pore meshes. They almost look similar to this. And this
9 filling of the space in between the filaments only by scar
10 tissue, that is what we call bridging, and this means, as
11 Joerg Holste said, increased risk for shrinkage and
12 chronic pain.

13 Q. And as both a surgeon and a biomaterials scientist,
14 have you treated patients that have had pain as a result
15 of fibrotic bridging like we see in this pathology slide?

16 A. Yes. We have made several explantations because of
17 pain, and mainly 90% of these were explants from heavy-
18 weight small-pore meshes.

19 Q. What is it about scarring in an implant like we see in
20 this slide that causes pain in patients?

21 MR. THOMAS: Your Honor, I object. Once again,
22 foundation.

23 THE COURT: Doctor, these explants of heavy
24 mesh WHEN you found pain before, from what area of the
25 body were they removed?

1 THE WITNESS: The meshes that I removed or we
2 removed in our department for pain, they were removed from
3 the abdominal wall.

4 THE COURT: All right. I'm going to allow it.

5 Ladies and gentlemen, I want you to know that his
6 opinion is based upon what he found to be a reaction in
7 the removal of a hernia mesh.

8 Go ahead.

9 BY MR. ANDERSON:

10 Q. Dr. Klingen, have you studied the tissue responses of
11 surgical meshes for the last 20 years?

12 A. Yes.

13 Q. Is there a difference in the tissue response, whether
14 it's an abdominal tissue or another tissue in the body,
15 when it comes to a foreign-body reaction to a foreign body
16 in a human's body?

17 MR. THOMAS: Objection, your Honor.

18 Foundation.

19 THE COURT: Overruled.

20 A. The basic tissue reaction is very, very similar, and
21 the principle of this bridging scar formation, this
22 filling out of the pores by scar, we saw it in the
23 animals, we saw it in hernia meshes, and we see it here in
24 a TVT sample. So, it is a confirmation of what can be
25 seen in all other parts of the body, as well.

1 Q. Based upon that, do you have an opinion to a
2 reasonable degree of medical and scientific certainty
3 whether or not what we're seeing in this could actually
4 lead to pain in the tissue?

5 MR. THOMAS: Objection, your Honor.

6 Foundation.

7 THE COURT: Overruled.

8 A. We know that the huge amount of scar tissue is a
9 serious -- or reason for chronic pain. The more scar --

10 THE COURT: Is that a yes or a no?

11 THE WITNESS: Yes.

12 BY MR. ANDERSON:

13 Q. Are you familiar with the term "mesh shrinkage"?

14 A. Yes.

15 Q. Is that something you've studied over the last 20
16 years?

17 A. Yes.

18 Q. Is that something that you studied while a consultant
19 with Ethicon?

20 A. Yes.

21 Q. Is that something that you studied while a consultant
22 with Ethicon in helping them to develop safer light-weight
23 large-pore meshes?

24 A. Yes.

25 Q. Is mesh shrinkage a basis for the development of not

1 only UltraPro, but Vypro, for hernia mesh patients?

2 A. Yes.

3 Q. And was mesh shrinkage something that was developed
4 with you and Ethicon that led to the development of a
5 light-weight large-pore mesh, Prolene+M -- Prolift+M for a
6 woman's prolapse?

7 MR. THOMAS: Your Honor --

8 A. Yes.

9 MR. THOMAS: -- I know he's trying to get this
10 done, but he's also leading him everywhere he's going, and
11 I think that's improper.

12 THE COURT: You know, everybody's led all day
13 long.

14 MR. THOMAS: I know that.

15 THE COURT: And it is, indeed, too leading, and
16 I'll sustain the objection, which is unusual for me.

17 BY MR. ANDERSON:

18 Q. Is this something that, when you were a consultant
19 with Ethicon, that you saw in the tissues of one explant?

20 A. Yes.

21 Q. And when you looked at the explants of Prolene, was it
22 both for Prolene mesh as well as --

23 MR. THOMAS: Your Honor?

24 THE COURT: Sustained.

25 BY MR. ANDERSON:

1 Q. Do you have another slide for us, sir?

2 A. Yes. So this slide has shown that --

3 MR. THOMAS: Excuse me, there's no question
4 pending, your Honor.

5 THE COURT: I'm sorry?

6 MR. THOMAS: There was no question pending.

7 MR. ANDERSON: Do you have another slide?

8 THE COURT: The question is do you have another
9 slide for us.

10 MR. THOMAS: And then he began to --

11 THE WITNESS: Sorry. Yes.

12 THE COURT: The answer is yes, that he's got
13 another slide.

14 Mr. Anderson?

15 BY MR. ANDERSON:

16 Q. Do you have a slide that was from Carolyn Lewis?

17 A. Yes.

18 Q. Okay. And do you have something that you believe will
19 be helpful in formulating your opinions as to what
20 happened in the tissue of Carolyn Lewis from the TVT?

21 A. Yes.

22 MR. ANDERSON: May he show it, your Honor?

23 MR. THOMAS: Objection. Foundation, your
24 Honor.

25 THE COURT: I will allow it.

1 BY MR. ANDERSON:

2 Q. What are we looking at here, Doctor?

3 A. One test performed is whether their shrinkage results
4 in a folding of the meshes, in a contraction of the mesh
5 material.

6 And what we see in this cross-cutting, that you have
7 several mesh areas or filament areas here which showed
8 that you have this folding there. It cannot be -- or I
9 cannot imagine any flat mesh area so that you, in a cross-
10 cutting, see the meshes in the orientation as it is seen
11 here.

12 So, this slide clearly shows that you have this
13 folding and this deformation of the mesh structure.

14 Q. And in your work as a hernia surgeon, has mesh
15 shrinkage like this -- have you seen this in explanted
16 histopathology slides?

17 A. Yes.

18 Q. And what does that mean for your hernia patients when
19 you see this in their tissue? What complications are we
20 referring to, Doctor?

21 A. The complication of this folding depends on the
22 location where it was -- where the mesh has been
23 implanted. But you have an increased risk for pain and
24 you have an increased risk for erosion of adjacent organs.

25 Q. Do you have any slides with you today that would show

1 any of these entrapped nerves that are from Ms. Lewis'
2 explant?

3 A. Yes.

4 Q. Would you please show those to us?

5 A. Yes. May I please --

6 Q. Yes.

7 A. What you see on this image, as well, is here you have
8 this blue marked foreign body. This is a particle. You
9 see this blue is the polymer which has not been removed by
10 the cutting process, and you see that there is already
11 a tissue reaction around. And these is a typical example
12 of these particles which result from the cutting of the
13 mesh during the manufacturing.

14 THE COURT: How can you tell it's a particle
15 instead of a cross-section of a fiber?

16 THE WITNESS: Because of these triple --
17 these -- the form of this one. When you have a cross-
18 cutting of the fiber, you usually have an ellipsoid or a
19 spherical conformation.

20 But these -- these parts -- the only explanation or
21 the most likely explanation is that this is one of the
22 loose ends that occurs when you cut a mesh out of a large
23 piece of mesh.

24 THE COURT: I also marked on your slide. The
25 jury saw my mark. Pay no attention to it.

1 THE CLERK: Oh, I'm sorry, I cleared it.

2 THE COURT: That's all right. That's okay. He
3 can put any new marks on it he wants.

4 THE CLERK: Okay.

5 THE COURT: Mr. Anderson.

6 MR. ANDERSON: Yes.

7 BY MR. ANDERSON:

8 Q. I was asking if you had any slides with you today
9 showing any entrapped nerves that you mentioned or scar
10 tissues surrounding nerves in Mrs. Lewis explant?

11 A. Yes.

12 Q. Can you show those to the jury?

13 MR. THOMAS: Your Honor, may I have a
14 continuing objection to this line of questioning on the
15 basis of foundation?

16 THE COURT: Yes.

17 MR. THOMAS: Thank you, your Honor.

18 BY MR. ANDERSON:

19 Q. Doctor, before we get started, are there particular
20 different types of stains that would help the pathologist
21 or the histopathologist be able to identify nerves on
22 human explants?

23 A. Yes.

24 Q. And what types of stains would those be?

25 A. There are various proteins available that marks

1 different parts of the nerves. What we used here is the
2 so-called S-100 staining that is -- that shows nerve-like
3 structures there. But there are others, as well.

4 Q. Okay. Can you please tell the jury what we're seeing
5 here on this S-100 staining from Ms. Lewis' explant?

6 A. As you see here, this one is the area where the mesh
7 fiber has been located. And this brown area here, these
8 are -- this is tissue that appears to be a small nerve.
9 And this is very, very small. You have here a
10 magnification of 40. So, this is about 10 to 20 microns.
11 Very, very small nerves. And no surgeon is able to see
12 these nerves.

13 And as you remember, all this area is transformed
14 into scar tissue, and these nerves are within the middle
15 of this scar tissue.

16 So, when you have the contraction of the scar
17 tissue, then this can result in irritation of these nerve
18 structures and cause chronic pain.

19 Q. In your work as a hernia surgeon, did you have
20 occasion to treat patients who had S-100 stainings that
21 appear the way this one does on the screen, sir?

22 A. Yes.

23 Q. Okay. And what did that mean for patient
24 complications in your hernia patients when they had an
25 S-100 that had entrapped nerves like we see here?

1 A. This is usually seen in patients where we remove the
2 meshes because of pain. And we have to remove the
3 meshes. And when we looked afterwards, made these tissue
4 analysis, we usually find this very closed neighborhood of
5 nerves and meshes and where the nerves are entrapped into
6 the scar tissue.

7 Q. In your training, even going back as early as medical
8 school, do you have any knowledge, sir, as to whether or
9 not these types of S-100 stainings would show entrapped
10 nerves in scar tissue anywhere in the body that there is
11 pain?

12 MR. THOMAS: Your Honor, he's leading.

13 THE COURT: Well, I'm not sure what you're
14 objecting to, but I'm simply going to tell the jury the
15 fact that something occurs at the same time as something
16 else doesn't mean it was caused by the something else.
17 And in order for an expert witness to say so, they must
18 hold that opinion based on sufficient expertise or say
19 that it is to a reasonable degree of medical certainty,
20 and be qualified to do so in their field.

21 I've allowed all of this testimony so far because I
22 thought it was helpful to you.

23 BY MR. ANDERSON:

24 Q. Do you have an opinion as to whether or not these
25 entrapped nerves in this slide indicate -- would indicate

1 chronic pain for Ms. Lewis?

2 MR. THOMAS: Objection, your Honor.

3 Foundation.

4 THE COURT: Sustained. Sustained.

5 BY MR. ANDERSON:

6 Q. Are entrapped nerves like this often related to pain
7 in your hernia patients?

8 A. Yes, we often find this relation.

9 MR. THOMAS: Your Honor, I'd move to strike the
10 last answer.

11 THE COURT: The motion to strike is granted.

12 The witness' prior testimony was that when the hernia
13 meshes were removed, they often found, upon examination,
14 slides that showed similar artifacts.

15 He did not opine that those artifacts, as found, if
16 I'm using the right word, were causally related to any
17 pain that his hernia patients suffered.

18 So the objection is sustained, and the explanation
19 was much too long. Sorry.

20 BY MR. ANDERSON:

21 Q. Are these artifacts that you see on the screen here
22 related to pain in your hernia patients?

23 MR. THOMAS: Objection, your Honor. It's not a
24 hernia patient. And foundation. He's not qualified to
25 give that opinion.

1 MR. ANDERSON: I'll withdraw the question, your
2 Honor.

3 THE COURT: All right.

4 BY MR. ANDERSON:

5 Q. Do you have any other slides that would show bridging
6 fibroses, mesh shrinkage or entrapped nerves from
7 Ms. Lewis's explant samples?

8 A. I ever two or three others which show the scar
9 formation --

10 MR. THOMAS: Your Honor, the answer is yes or
11 no, as opposed to his explanation.

14 BY MR. ANDERSON:

15 Q. Do you have any other slides that would show either
16 bridging fibrosis, scar plate formation or mesh shrinkage
17 from Ms. Lewis?

18 | A. Yes.

19 Q. Do you think those would be helpful to the jury in
20 formulating your opinions?

21 A. They look almost similar to the one before, so it's
22 always similar appearing, the way you have these closed
23 distance.

24 Q. Do you have an opinion to a reasonable degree of
25 medical certainty as to whether or not the images that

1 we've seen on the screen today would relate to any
2 complications of pain in Ms. Lewis?

3 MR. THOMAS: Objection, your Honor.

4 Foundation. It's not his area of expertise.

5 THE COURT: With the caution, ladies and
6 gentlemen, that I previously gave you, I will allow the
7 answer.

8 BY MR. ANDERSON:

9 Q. Do you have an opinion, first of all, sir?

10 A. Yes.

11 Q. And what is that opinion?

12 A. The opinion is that the excessive scar formation that
13 we have found to be the major cause of many complications,
14 that this is found in these samples in this case, as well.

15 We saw the scar formation, the deformation, the
16 folding, the particle loss.

17 So, all these things that we found were the
18 disadvantages of over-engineered meshes. In animals' --

19 MR. THOMAS: Your Honor, going far beyond the
20 question that was asked.

21 THE COURT: Well, and also --

22 MR. THOMAS: I move to strike it.

23 THE COURT: I sustain the objection.

24 BY MR. ANDERSON:

25 Q. I asked you if you have an opinion in that regard.

1 What is your opinion with regard to the slides which
2 you've seen here with regard to -- strike that. Let me
3 see if I can ask it again.

4 Do you have an opinion to a reasonable degree of
5 scientific certainty as to whether or not the slides that
6 we've just seen, the S-100 slides, and the H&E slides
7 regarding nerve entrapment, mesh shrinkage and bridging
8 fibrosis, as to whether or not those would lead to chronic
9 pain in Ms. Lewis?

10 MR. THOMAS: Objection, your Honor.

11 THE COURT: I overrule the objection.

12 BY MR. ANDERSON:

13 Q. Do you have an opinion?

14 A. Yes.

15 Q. And what is the opinion?

16 A. The opinion is that these findings can very good
17 explain the manifestation of pain.

18 THE COURT: I'll sustain the objection and
19 strike the answer. The jury will disregard.

20 MR. ANDERSON: No further questions.

21 THE COURT: Can explain -- can explain is not
22 the --

23 BY MR. ANDERSON:

24 Q. Do you have an opinion to a reasonable degree of
25 scientific certainty as to whether or not --

1 THE COURT: I've got your objection.

2 MR. ANDERSON: No further questions.

3 THE COURT: Okay, cross-exam.

4 MR. THOMAS: I'm going to be to be a little
5 while, your Honor.

6 THE COURT: What?

7 MR. THOMAS: I'm going to be a little while.

8 THE COURT: Well, take four minutes of it now.

CROSS-EXAMINATION

12 BY MR. THOMAS:

13 Q. Good afternoon, Dr. Klinge. The slides that you've
14 just been talking to the jury about, you didn't prepare
15 those slides, did you?

16 A. No.

17 Q. As a matter of fact, those slides were prepared by
18 another pathologist, weren't they?

19 A. Yes.

20 Q. They were prepared by a Dr. Kreitzer from Connecticut;
21 is that correct?

22 A. Yes.

23 Q. And Dr. Kreitzer is a board-certified pathologist in
24 Connecticut, isn't he?

25 A. Yes.

1 Q. And you've never met Dr. Kreitzer?

2 A. No.

3 Q. You've never spoken to him, have you?

4 A. No.

5 Q. You have not had any communications at all with
6 Dr. Kreitzer about the slides that you discussed with the
7 jury that he prepared, which you just discussed. Fair?

8 A. Sir, will you --

9 Q. I'm sorry. I'll try again. You have not had any
10 communications at all with Dr. Kreitzer about the slides
11 which you just discussed with the jury?

12 A. No.

13 Q. Now, You don't have --

14 A. That is not correct.

15 Q. Oh, you have spoken with Dr. Kreitzer?

16 A. No. But it's a communication. I got a -- a paper
17 from him where he clearly documented which slides he
18 prepared with -- with his technique.

19 Q. Okay. But it was only identifying the slides you
20 received and the technique he performed; correct?

21 A. Yes.

22 THE COURT: Let me ask the jury just a second
23 and interrupt you. I apologize.

24 Since you're staying in town, would you like to
25 finish this witness today? It will probably take another

1 half-hour. If you wouldn't, I certainly understand.

2 All right, let's finish the witness.

3 MR. THOMAS: Thank you, your Honor.

4 BY MR. THOMAS:

5 Q. You're not a pathologist; correct?

6 A. Correct.

7 Q. You don't have a residency in pathology; correct?

8 A. Correct.

9 Q. You don't have a fellowship in pathology; correct?

10 A. Correct.

11 Q. You're not board-certified in pathology?

12 A. Correct.

13 Q. You've never been a reviewer or an editor of a
14 pathology journal, have you?

15 A. That is not correct. I have been a reviewer of a
16 histopathology journal.

17 Q. Could I have your deposition, please -- of Lewis
18 deposition, page 562, line 24. Lines 22 to 24.

19 Now, I came to Germany and took your deposition, and
20 I asked you a question: "Have you ever been an editor or
21 a reviewer of a pathology journal?"

22 You answered no at that time?

23 A. Yes.

24 Q. Is that the answer you gave then?

25 A. I have to correct it.

1 Q. Go ahead.

2 A. There is one journal from a Spanish editor who asked
3 me to make a review of some manuscripts that are sent to
4 him. So.

5 Q. So, the answer that you gave to me at your deposition
6 was incorrect; is that fair?

7 A. Yes.

8 Q. Okay. Now, you work at a hospital?

9 A. Yes.

10 Q. And you used to be a surgeon; correct? Excuse me, you
11 used to operate on patients; correct?

12 A. I have -- have been operating patients, yeah.

13 Q. But you haven't performed any surgeries since 2006;
14 correct?

15 A. That is correct.

16 Q. And there are pathologists at the hospital where you
17 work, aren't there?

18 A. There is a few, yes.

19 Q. And at the hospital where you work, you were not
20 permitted to sign pathology reports; correct?

21 A. That is correct.

22 MR. THOMAS: May I approach, your Honor?

23 THE COURT: You may.

24 BY MR. THOMAS:

25 Q. Dr. Klingen, I've handed what has been marked as Joint

1 Exhibit 10020A.263.

2 THE COURT: Did you get all that, Robin?

3 THE CLERK: No.

4 MR. THOMAS: Joint Exhibit 10020A.263. And I
5 think this is a stipulated medical record, your Honor.

6 THE COURT: All right.

7 BY MR. THOMAS:

8 Q. Do you have that in front of you?

9 A. Yes.

10 Q. And this is the pathology report from the hospital
11 where Ms. Lewis had her mesh explanted; correct?

12 A. Yeah, that is correct.

13 Q. And a pathologist, a real pathologist, looked at the
14 pathology upon the explant and prepared this report?

15 A. That is correct.

16 Q. And it's true that there are none of the findings in
17 this report that you've told this jury about today?

18 A. That is true.

19 MR. THOMAS: Judge, give me just a second. I
20 thought I was going to be hear for four minutes and now
21 I'm going to be here for 30.

22 (Pause.)

23 BY MR. THOMAS:

24 Q. Now, Dr. Klinge, you've actually used mesh to treat
25 hernia patients, haven't you?

1 A. Yes.

2 Q. And the use of mesh to repair hernias is an important
3 option for hernia patients, isn't it?

4 A. Yes.

5 Q. And polypropylene mesh is the most widely used
6 material for hernia repairs; isn't that true?

7 A. That is true.

8 Q. And mesh implants made of polypropylene monofilament
9 fiber have been used in the human body since 1963?

10 A. Yes.

11 Q. And Prolene mesh is a polypropylene monofilament
12 fiber; correct?

13 A. It's double filament, would be more accurate.

14 Q. You say it's not a monofilament fiber?

15 A. Yeah, it's a monofilament, but it's two. It's always
16 two fibers running close together. So, in some
17 manuscripts it's called double filaments.

18 Q. Now, there are two ways to repair hernias in terms of
19 mesh and native tissue repair. You understand that, don't
20 you?

21 A. Very well.

22 Q. And native tissue repair you use sutures to put the
23 hernia back into place?

24 A. Yes.

25 Q. And sutures is the same thing as stitches; correct?

1 What we call stitches here in the United States?

2 A. I have to -- I believe it.

3 Q. All right. And you can use Prolene sutures to repair
4 a hernia, just like you can use Prolene mesh to repair a
5 hernia; correct?

6 A. In some patients.

7 Q. Yes. And you've performed about 200 native tissue
8 repairs?

9 A. Yes.

10 Q. And you've performed about 300 hernia repairs using
11 mesh; correct?

12 A. Yes.

13 Q. And you've placed Prolene mesh for hernia repair about
14 five times?

15 A. Yes.

16 Q. And when you were doing hernia surgery, you knew there
17 were risks to that hernia surgery; true?

18 A. Yes.

19 Q. And when you used polypropylene mesh for hernia repair
20 for your patients, you believed that the benefits
21 outweighed the risks to those patients; correct?

22 MR. ANDERSON: Objection, your Honor. May we
23 approach?

24 THE COURT: Yes.

25 SIDEBAR CONFERENCE:

1 THE COURT: All right, sir.

2 MR. ANDERSON: Because of your Honor's ruling
3 at the beginning of this, I changed my entire presentation
4 and outline because I removed everything that would be
5 cumulative from Dr. Klosterhalfen's deposition, because
6 your Honor instructed me that I had to do that. So, I
7 significantly altered my entire presentation and just
8 talked about pathology.

9 I specifically did not go into his hernia work. I
10 did not go into light-weight, large-pore. I did not go
11 into those areas that Mr. Thomas listed on his sheet that
12 would be cumulative. And now Mr. Thomas is seeking to go
13 into all those areas and bring them in, even though he
14 didn't want me to talk about. So I think it's patently
15 unfair. We talked about pathology.

16 THE COURT: Well, the record will reflect what
17 I ruled with regard to the testimony, but you did explore
18 with him the basis for his opinions, which, to a large
19 extent, were based upon his history performing hernia
20 surgeries.

21 And as to the opinions he offered, he based his
22 opinions, to a large extent, if I'm not mistaken, on his
23 experience in doing hernia surgeries and hernia explants.
24 And that was true even as to his opinions regarding
25 Mrs. Lewis.

1 Now, I grant you, I'm not keen on spending a lot of
2 time talking about hernias. I wasn't when you were doing
3 it. I'm not now. But it is fair for him to cross-examine
4 this witness to emphasize to the jury that he believes
5 that a hernia surgeon, which is what he's trying to do,
6 doesn't know what he's talking about when he's dealing
7 with this other kind of mesh.

8 It's all -- the chess pieces are moving very nicely.
9 You guys are good. I overrule your objection. But -- but
10 don't --

11 MR. THOMAS: I'm not going to abuse it, your
12 Honor.

13 MR. ANDERSON: He's getting into patient
14 selection, he's getting into risk-benefit analysis, and I
15 didn't discuss any of those things.

16 THE COURT: Well, I'm going to allow this --
17 I'm going to allow the pending question.

18 END OF SIDEBAR CONFERENCE.

19 THE COURT: There's a question pending. Do you
20 want it read or do you remember it?

21 MR. THOMAS: I need it read, your Honor.

22 THE COURT: All right.

23 COURT REPORTER: And when you used
24 polypropylene mesh for hernia repair for your patients,
25 you believed that the benefits outweighed the risks to

1 those patients; correct?

2 A. Yes, but it changed over time, significantly.

3 Q. Now -- thank you. Just so the record is clear, you've
4 never performed surgery for the repair of stress urinary
5 incontinence; true?

6 A. That is correct.

7 Q. And you've not studied the rates of complications
8 associated with the use of mesh for the treatment of
9 stress urinary incontinence?

10 A. That is correct.

11 Q. And you are unaware of any clinical studies that show
12 the use of Prolene mesh increases the risk of injury to a
13 patient in the treatment of stress urinary incontinence
14 over a larger pore, light-weight mesh; true.

15 A. This is true, but impossible.

16 Q. You've talked a little bit about your collection of
17 hernia explants. You do maintain a collection of hernia
18 explants at the university; correct?

19 A. Yes.

20 Q. And you had about 600 when we talked last?

21 A. Yes.

22 Q. And you have not attempted to collect any mesh
23 explants from patients with pelvic organ prolapse or
24 stress urinary incontinence; true?

25 A. That's true.

1 Q. Now, none of your work for the period -- strike that.
2 I'll withdraw that.

3 Now, when you performed hernia surgery, you
4 understood that mesh could shrink or contract, didn't you?

5 A. Yes.

6 Q. And contraction is a risk of any hernia surgery. Do
7 you agree with that?

8 A. That is true in principle, but not in quantity.

9 Q. But -- and you do not know the rate of complications
10 from contracture or shrinkage in the placement of mesh
11 with the treatment of stress urinary incontinence; true?

12 A. We know that it causes complications.

13 Q. No, excuse me, I asked you a question, a very specific
14 question, Doctor.

15 You do not know the rate of complications from
16 contracture or shrinkage in the placement of mesh for the
17 treatment of stress urinary incontinence?

18 A. It's not possible, so, therefore, yes.

19 Q. Therefore, no, you don't know?

20 A. Yes, you are right. No, I don't.

21 Q. Thank you. That helps me.

22 You're not aware of any literature testing the
23 impact of particle loss in vivo for an Ethicon mesh used
24 for the treatment of stress urinary incontinence; true?

25 A. True.

1 Q. Now, You said you've implanted mesh about 300 times in
2 hernia surgery. And when you used the mesh for the
3 treatment of hernias, you usually trim the mesh; correct?

4 A. Yes.

5 Q. And you use scissors to trim the mesh to size it so
6 that you can place it in the hernia; correct?

7 A. Yes.

8 Q. And when you trim the mesh, particles come off of the
9 mesh?

10 A. But it varies from the mesh.

11 Q. And there are about 20 million hernia surgeries each
12 year?

13 A. There are 20 million mesh implantations. That is the
14 last estimate. That's not all only hernia.

15 Q. And for a large number of those you would expect the
16 surgeons to be trimming that mesh before they implant it,
17 wouldn't you?

18 A. Yes.

19 Q. And in the 20 years of mesh research that you've done,
20 you've never studied the clinical effects of particle loss
21 from mesh; true?

22 A. It's possible, yes.

23 Q. And you've never made a systematic analysis to measure
24 the extent to which Ethicon meshes used in the treatment
25 of stress urinary incontinence shed particles in the human

1 body; true?

2 A. True.

3 MR. THOMAS: Your Honor, may I approach the
4 witness?

5 THE COURT: You may.

6 BY MR. THOMAS:

7 Q. Dr. Klinge, I've handed you a book. The book is a
8 2010 book called *Hernia Repair Sequellae*. Do you
9 recognize that?

10 A. Yes.

11 Q. Published in 2010?

12 A. Yes.

13 Q. And the first author is Volker Schumpelick?

14 A. He's the editor.

15 Q. Editor. And he was your boss at Aachen, is that
16 right, the head of the department?

17 A. At that time, yes.

18 Q. And would you turn to page 439? I've marked it for
19 you.

20 MR. THOMAS: And, Jamie, it's Defendant's
21 Exhibits 30719, and the page is .3.

22 Q. And the book chapter is Alloplastic Implants for the
23 Treatment of Stress Urinary Incontinence and Pelvic Organ
24 Prolapse. Do you see that?

25 A. Yes.

1 Q. And you're one of the authors of that chapter of the
2 book?

3 A. Yes.

4 MR. THOMAS: Jamie, if you would go to the next
5 page, which is .4.

6 BY MR. THOMAS:

7 Q. And if you go to the right column, it says, "Mesh used
8 in the treatment of stress urinary incontinence." And if
9 you go down to the second full paragraph --

10 A. Yes.

11 Q. -- let's read that together. It says, "At present,
12 the gold standard in SUI surgery is the suburethral sling,
13 using either the tension-free vaginal tape with the
14 tension-free" -- excuse me. Let me start over again.

15 "At present, the gold standard in SUI surgery is the
16 suburethral sling, using either the tension-free vaginal
17 tape, TVT" -- that's the Ethicon Dynacare product, isn't
18 it?

19 A. Yes.

20 Q. -- "or the transobturator tape, TOT technique. The
21 two procedures do not seem to differ in terms of efficacy,
22 with TOT being advantageous because of the lower rate of
23 bladder injuries."

24 And you wrote that in 2010; correct?

25 A. Yes.

1 Q. Now, the jury has heard a little bit about a company
2 known as FEG. You have done research for FEG since 1994,
3 haven't you?

4 THE COURT: That's what he said on direct. Go
5 ahead.

6 MR. THOMAS: With FEG? I'm sorry?

7 THE COURT: Yes.

8 MR. THOMAS: Thank you, your Honor.

9 BY MR. THOMAS:

10 Q. And you helped FEG develop PVDF mesh, didn't you?

11 A. Yes.

12 Q. And FEG has a patent on the PVDF mesh?

13 A. Yes.

14 Q. And you were named on that patent; correct?

15 A. Yes.

16 Q. You've been a paid consultant for FEG since 1998 or
17 1999; true?

18 A. No, that's not true.

19 Q. You've received 20,000 euros or deutschmarks per year
20 from 2000 to 2005; is that true?

21 A. That is -- from FEG? This is not true. 2000 to 2005,
22 that is -- that has been -- that was a contract with
23 Ethicon.

24 MR. THOMAS: Jamie, could you bring up the
25 gross trial transcripts, 103, 6 to 12, please?

1 (Pause.)

2 BY MR. THOMAS:

3 Q. I'm sorry. You're right. I apologize. That's my
4 mistake.

5 Today you're compensated by FEG; is that true?

6 A. Yes.

7 Q. They pay you about 30,000 euros a year?

8 A. Approximately, yes.

9 Q. And that's about a little less than half of your
10 annual salary at the university?

11 A. That's less.

12 Q. And FEG decides how much money it's going to pay you
13 each year; is that true?

14 A. Yes.

15 Q. And the amount FEG pays you each year depends on how
16 well the company does that year; true?

17 A. Yes.

18 Q. And you've spoken at conferences sponsored solely by
19 FEG; true?

20 A. Yes.

21 Q. And you you've spoken recently at conferences for FEG
22 promoting FEG meshes; true?

23 A. Promote? Maybe.

24 Q. Pardon me?

25 A. Maybe.

1 Q. Maybe. Well, you've worked with Prof. Jaeger in
2 developing a new PVDF mesh for the treatment of stress
3 urinary incontinence, didn't you?

4 A. It was a development of a new procedure using a
5 specifically developed device; but it was the presentation
6 of a procedure.

7 Q. And you worked on the Jaeger device at the request of
8 FEG, didn't you?

9 A. Yes.

10 Q. And you didn't charge FEG for the time you spent
11 working on that, did you?

12 A. No.

13 Q. You have had occasion to work with both FEG and
14 Dr. Klosterhalfen on different products; correct?

15 A. I didn't get the whole sentence.

16 Q. I'm sorry, you've had occasion to work with FEG and
17 Dr. Klosterhalfen with different projects; is that true?

18 A. I have occasion?

19 Q. You've done it on different times? Have you worked
20 with FEG and Dr. Klosterhalfen on different projects over
21 the years?

22 A. Yes.

23 Q. And you also worked with FEG and Prof. Klosterhalfen
24 in the preparation of a video; correct?

25 A. Yes.

1 Q. And you used that video presentation in your slide
2 shows sometimes?

3 A. Yes.

4 Q. And you've --

5 A. It's free. And it's free on the Internet. Everyone
6 can do it.

7 Q. And FEG paid for that?

8 A. They paid for the manufacturing of this video, yes.

9 Q. And to this day you are and continue to be a
10 consultant to FEG; true?

11 A. Yes.

12 MR. THOMAS: Your Honor, may I have a moment?

13 THE COURT: Yes.

14 MR. THOMAS: That's all the questions I have.
15 Thank you, Doctor.

16 THE WITNESS: Thank you.

17 THE COURT: All right. Mr. Anderson?

18 REDIRECT EXAMINATION

19 BY MR. ANDERSON:

20 Q. Dr. Klingen, in the article that counsel mentioned to
21 you about alloplastic materials with Dr. Schussler, do you
22 recall that part of your testimony?

23 A. Yes.

24 Q. What is Dr. Schussler's profession?

25 A. Dr. Schussler is the head gynecologist in Lucerne, in

1 Switzerland.

2 Q. And in that article, were you responsible for part of
3 the article and was he responsible for a different part?

4 A. He's responsible for the evaluation of the surgical
5 technique and I was introduced in this team of authors
6 because of my experience with the materials.

7 Q. And, in 2010, the mechanically cut mesh was no longer
8 on the market, was it, sir?

9 MR. THOMAS: Objection, your Honor. It's not
10 only beyond the scope of anything, it's just not true.

11 THE COURT: I don't know -- I mean, let me see
12 the book. I don't -- let me see what the quote said.
13 Could I see the book.

14 Thanks, Doctor.

15 I don't see anything in here about whether it was
16 machine cut or hand cut, or whatever.

17 MR. ANDERSON: And that's my point. From that
18 article, we can't tell whether or not the slings that
19 Dr. Schussler's talking about were the mechanical cut
20 meshes or were the laser cut meshes.

21 THE WITNESS: From my understanding, this -- he
22 described the technique of placing a tape there, but this
23 is not specific for a product. And on my discussions with
24 Prof. Schussler we used the term TVT as an example for a
25 procedure.

1 MR. THOMAS: Your Honor --

2 THE COURT: The jury will disregard the
3 elaboration and ignore the last part of the statement.

4 BY MR. ANDERSON:

5 Q. Counsel showed you the pathology report from Ms. Lewis
6 on cross-examination. Do you recall that?

7 A. Yes.

8 Q. Is it typical for pathology departments at hospitals
9 to report on things like bridging fibrosis?

10 MR. THOMAS: Objection, your Honor.

11 Foundation. He's not a pathologist in a hospital.

12 MR. ANDERSON: I'll withdraw the question.

13 THE COURT: All right.

14 BY MR. ANDERSON:

15 Q. As part of being a hernia surgeon at Aachen University
16 and Aachen University Hospitals in Aachen -- strike that.

17 How large is Aachen University Hospital?

18 A. It has about 1,500 beds in hospital.

19 Q. And while you were practicing as a hernia surgeon
20 there, did you receive explant reports back -- I'm sorry,
21 pathology reports back from individuals who had had mesh
22 explanted from them?

23 A. Yes, we would teach with it.

24 Q. And did the pathologists in your pathology department
25 typically respond and report on things like tissue

1 response, bridging fibrosis and scar plate formation?

2 MR. THOMAS: Objection, your Honor.

3 Foundation. Didn't have anything to do with the Carolyn
4 Lewis case. Didn't have anything with the pathology
5 report from Texas.

6 THE COURT: I'll allow him to answer the
7 question, but don't go any further.

8 You may answer.

9 BY MR. ANDERSON:

10 Q. You may answer.

11 A. This is the general statement of pathologists, who are
12 not interested in the specific details to cause to write
13 the tissue response.

14 MR. THOMAS: Your Honor?

15 A. And that is what I've seen.

16 THE COURT: If I understood his answer, which I
17 think I did, he said the pathologists aren't interested in
18 those specific details?

19 MR. ANDERSON: That's right.

20 THE COURT: Yes.

21 MR. ANDERSON: No further questions.

22 THE COURT: All right. Anything else?

23 MR. THOMAS: Nothing, your Honor.

24 THE COURT: All right. Thank you, very much,
25 Doctor, you may step down. May the witness be excused?

1 MR. ANDERSON: Yes, your Honor.

2 THE COURT: Ladies and gentlemen of the jury,
3 we've come to the end of the day. I really hope you have
4 a nice meal and a nice time.

5 This is difficult. It's compounded by difficult
6 weather. It is a duty of citizenship. And I hope, at the
7 end, you will say, as most jurors in federal court say,
8 I'm glad I did it, but I don't want to ever do it again.

9 Please have a pleasant evening. Do not discuss the
10 case. Watch TV, listen to the radio, read the newspapers.
11 Do not talk to anybody about the case. Do not read social
12 media that might involve any discussion of the case.
13 Don't communicate with anybody by any electronic or other
14 means concerning the case.

15 I feel like some kind of -- one of those recordings,
16 because I say it over and over again. But it is so
17 important that it bears repeating. You only can
18 deliberate on this case when you're back in the jury room
19 at the end of all of it, and all 12 of you can then start
20 at the same time talking about it.

21 And you know that's worked very well for well over
22 200 years, and I think it will work well in this case.

23 Have a pleasant evening. I'll see you at 9 o'clock.

24 Court is in recess, adjourned for the day, whatever.

25 (Proceedings concluded at 5:30 p.m.)

1 CERTIFICATE OF OFFICIAL REPORTERS
23 Teresa M. Ruffner and Harold M. Hagopian do hereby
4 certify that the foregoing is a true and correct
5 transcript, to the best of our abilities, from the record
6 of proceedings in the above-entitled matter.
78 s/Teresa M. Ruffner
9 ReporterFebruary 13, 2014
Date10 s/Harold M. Hagopian
11 ReporterFebruary 13, 2014
Date12
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